# AN OPEN NON RANDOMIZED CLINICAL TRIAL OF MAAMPISIN CHOORANAM IN PITHA PERUMBADU (MENORRHAGIA)

The dissertation submitted by

**Dr. A. DHIVYABHARATHI (Reg. No. 321511103)**

Under the Guidance of

**Prof. Dr. K. KANAKAVALLI, M.D.(S)**

Submitted to

**THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY**

In partial fulfillment of the requirements
For the award of the degree of

**SIDDHA MARUTHUVA PERARIGNAR**

**DOCTOR OF MEDICINE (SIDDHA)**

**BRANCH I – MARUTHUVAM**

**POST GRADUATE DEPARTMENT OF MARUTHUVAM**

**THE GOVERNMENT SIDDHA MEDICAL COLLEGE**

**CHENNAI – 106**

**OCTOBER - 2018**

# CERTIFICATE

This is to certify that the dissertation entitled **"AN OPEN NON-RANDOMIZED CLINICAL TRIAL IF MAAMPISIN CHOORANAM IN PITHA PERUMBADU (MENORRHAGIA)"** is a bonafide work done by Dr. A.**DHIVYABHARATHI** Government Siddha Medical College, Chennai – 600106 in partial fulfillment of the University rules and regulations for award of **SIDDHA MARUTHUVA PERARIGNAR** under my guidance and supervision during the academic year 2015 -2018.

Name & Signature of the Guide

Name & Signature of the HOD

Name & Signature of the Principal

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# ACKNOWLEDGEMENT

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First and foremost I am so grateful to **My Parents**, **Lord** and also express my thanks to **Siddhars** who gave me the strength and owing me with his blessings to complete this dissertation work.

I wish to express my gratitude to honorable **Dr. P. Parthiban, M.D(S),** Join director, Department of Indian Medicine and Homeopathy for his valuable guidance, encouragement and moral support.

I express my gratitude to my guide Prof. **Dr. K. Kanakavalli, M.D(S),** Principal Govt.Siddha Medical College, Chennai-106 for her support and permission for carrying out this study.

I deeply express my gratitude to Prof. **Dr. N. Anbu, M.D(S),** Head of the Department, PG Maruthuvam, Govt.Siddha Medical College, Chennai-106 who helped me at all stages of my studies. I am very much thankful to him for his timely suggestions, patience, encouragement and scholarly guidance.

I do extend my thanks to **Dr. U. Chitra, M.D(S),** Lecturer Grade II for her valuable ideas for this study.

I wish to express my thanks to **Dr. R. Menaka, M.D(S)** Lecturer Grade II for her useful suggestions during the period of the study.

I wish to express my thanks to **Dr. S.M. Chitra, M.D(S),** Lecturer Grade II for her useful suggestions during the period of the study.

I wish to thank **Dr. R. Sasirekha, M.D(S),** Lecturer Grade II for her support and guidance.

I wish to express my special thanks to **Dr. Vidhya, MBBS, DMRD**, Arignar Anna Govt.Hospital of Indian Medicine, Chennai-106 who guided me and cleared my doubts regarding the ultra sound scan.

My special thanks to **Dr. P. Sathyarajeswaran, M.D(s),** Clinical Research Scientist, CCRS, Chennai for his encouragement and support during the period of study.

I express my thanks to **Dr.P. Muralidaran**, C.L.Baid Metha College of Pharmacy, Chennai, Tamilnadu, India who helped to do pharmacological and toxicological studies.

I thank to **Dr. S. Sunil kumar**, **Research Officer**., Dept. of Pharmacognosy, CCRS, Arumbakkam, Chennai for authenticating drug.

I also convey my thanks to **Dr. P.Kabilan M.D(s),** Professor and Head, Dept of Siddha, TamilNadu Dr.MGR Medical University, Guindy, Chennai-106 for doing physicochemical and phytochemical analysis for my trial medicine.

I like to thank, Prof. **S. Selvaraj, M.Sc, M.Phil**, HOD, Department of Biochemistry, Government Siddha Medical College, Arumbakkam – 106 for my biochemical analysis.

I thank to **Dr. D. Charlotte Vivilia**, **BSMS, M.Sc (Epidemology )** for her help in arriving the Biostatistics.

I thank to all the teaching staff of PG Department of Maruthuvam, GSMC, Chennai. I sincerely thank to all my patients who co-operated for the successful completion of this study.

I like to thank all the patients for eagerly accepting themselves and gave a full support for complete the study.

I extend my thanks to **Mr. Dhandayuthapani, M.com**., MLIS. Librarian of Dr. Ambedkar Central Library, Anna Hospital campus, Arumbakkam for his help in literature survey.

Last and most importantly, I am indebted to all my patients for willingly accepting themselves for this study.

Finally I would like to thank all of my friends and batch mates for their kind support and co-operation.

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# CONTENTS

# INTRODUCTION

# INTRODUCTION

**"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"** is the widely accepted definition of health given by World Health Organisation [(1)].

Siddha System of Medicine is the first system to emphasize health as the perfect state of physical, psychological, social and spiritual component of a human being. It accentuates not only a healthy body but also a peaceful mind. Hence, it is unique when compared to other medical system. It is the traditional medical system widely practiced by the people of Tamil Nadu nowadays. It doesn't consider treatment and prevention separately. The main aim of this system is prevention of disease, alike the proverb - Prevention is better than cure.

It is a multidisciplinary system which comprises knowledge from various subjects like chemistry, astrology, cosmology, physics, psychology, spirituality, philosophy, botany, etc.

Siddhars were spiritual adepts who possessed the Ashta Siddis, or the eight supernatural powers which could keep the body strong and perfect for External life, where there is no Death or Rebirth. According to the Scriptures, there were 18 principle Siddhars. Of these 18, Sage Agasthiyar is considered as one of the prominent leader.

The word "Siddha" is derived from the word "Siddhi" which literally means attaining perfection of life or heavenly Bliss. The ultimate aim to attain eternal bliss, by protecting human body from ageing, degeneration, disease & death and to achieve longevity with the admixture of preventive (with attanga yoga), Curative ( with herbs, minerals, metals and jeevam medicines), rejuvenation (with kaya kalphas) in the form of well- organized system of medicine called siddha system of medicine.

According to the Siddha medical science, the human body is the replica of the universe and built physiologically active by 96 thathuvas. The universe originally consisted of atoms which contributed to five basic elements viz earth, water, fire, air and ether ( panjaboodhas) which corresponded to the five senses of the human body and they

were the fundamental to all things in the world. Hence Siddhar Sattamuni in his text Satta Muni Gnanam says,

"அண்டத்திலுள்ளதே பிண்டம்

பிண்டத்திலுள்ளதே அண்டம்

அண்டமும் பிண்டமும் ஒன்றே

அறிந்துதான் பார்க்கும்போதே[(2)]"

The physiological function of the human body is mediated by three humors - Vatha, Pitha and Kapha and Seven physical constituents. They are related to Arusuvaigal and Panjaboodhas. Under normal conditions, the ratio between these three humors i.e.: (Vadham, Pitham, Kabam) 1:1/2:1/4 respectively. The maintenance of their normal order ensures the preservation of health and harmonious functioning of the body. When the equilibrium of three humors is disturbed, disease is occurred. This is what Saint Thiruvalluvar says,

"மிகினும் குறையினும் நோய்செய்யும் நூலோர்

வளி முதலா எண்ணிய மூன்று''[(3)]

மருந்து அதிகாரம் – திருக்குறள்

Another salient feature of Siddha medicine is 'Food as medicine; medicine as food'.

"உணவே மருந்து; மருந்தே உணவு"

- பழமொழி

The food which the human body takes and also the drugs used for the disease are all made of these five elements (panjaboodhas). Thus as per Siddha every drug is made up of panjabhoodas and has got the following properties. They are suvai( taste), gunam (character), veeriyam(potency), pirivu(bio-transformation) and magimai(special property). These drugs are obtained from the natural sources for medicinal purposes viz., Herbal origin, Metals and minerals origin, zoological origin. Diet and life style play a

major role not only in health but also in curing disease and various psychological and physiological functions of the body.

In Siddha System of medicine, Eight diagnostic methods ( Naadi, sparisam,na, niram, mozhi, vizhi, malam, moothiram) mentioned by Theraiyar, Neerkuri and Neikuri are the wonderful diagnostic tools to rule out the diseases, before the signs and symptoms appear.

Siddhars classified diseases in different categories and accounted for total 4448 diseases in human body. Among them, the diseases of the women pertaining to the reproductive organs also explained. Perumbadu Rogam which was explained by the great saint Yugi Muni in his text Vaithya Chinthamani is one of the important gynecological the problems that clinically correlate with MENORRHAGIA in Modern System of Medicine. A healthy woman only can produce a healthy generation. Being a woman, I prefer to take PITHA PERUMBADU (Menorrhagia) as my dissertation which is a main gynecological problem nowadays and also to give a solution through our Siddha System of Medicine.

Menorrhagia is defined as cyclic bleeding at normal intervals: the bleeding is either excessive in amount (> 80ml) or duration (> 7 days) or both. The term Menostaxis is often used to denote prolonged bleeding [(4)].

The WHO reports that 18 million women aged 30-55 years perceive their menstrual bleeding to be exorbitant.[(5)] Totally 30% of worldwide population having heavy menstrual blood loss.[(6)] In developing countries like India, about 20% of DUB cases are seen among adolescent and 40% among women above 40 years[(7)].

In Modern System of Medicine, as surgical intervention is the only choice, I had selected MAAMPISIN CHOORANAM a Poly herbal formulation from Siddha Vaidhiya Pathartha Guna Vilakkam- Moola Vargam to give best solution for Perumbadu. So there is a need to evaluate the safety and therapeutic efficacy of this classical Siddha formulation “Maampisin Chooranam” for scientific validation.

# AIM
# AND
# OBJECTIVES

# AIM AND OBJECTIVES

**AIM:**

The aim of the dissertation study is to analyse the selected disease PITHA PERUMBADU, both clinically and experimentally with the trial medicine MAAMPISIN CHOORANAM.

**OBJECTIVES:** To evaluate the therapeutic efficacy of MAAMPISIN CHOORANAM in PITHA PERUMBADU (MENORRHAGIA).

To collect the various Siddha literatures as well as Modern literatures

Herbal identification and authentication

Preparation of Maampisin Chooranam

Biochemical and physiochemical analysis

Toxicological and Pharmacological studies

To study the clinical course of the disease with observation on the etiology, classification, pathology, differential diagnosis, prognosis, complications and treatment by Siddha aspect.

To have an idea about the incidence of the disease with age, occupation, economical status, habits, family history and climate conditions.

To expose the clinical diagnostic methods mentioned by Siddhars to know how the disease manifest due to the deranged Mukkutram, Pori pulangal and Ezhu Udal thathukkal.

To have the modern parameters to confirm the diagnosis and prognosis of the disease

To have a clinical trial on the disease Pitha Perumbadu with the Siddha medicine MAAMPISIN CHOORANAM

To subject all patients for thorough investigation before and after treatment

To find out the statistical analysis and efficacy of the drug through clinical study

# REVIEW OF LITERATURE

# SIDDHA ASPECT

# REVIEW OF LITERATURE

## SIDDHA ASPECT

### பெரும்பாடு

### IYAL (DEFINITION)

Perumbadu is defined as the excessive loss of menstrual bleeding which may be increased in duration of menstrual bleeding or heavier blood flow without any change in the cycle length [8].

### NOI VARUM VAZHI (AETIOLOGY)

**Yugi vaidhiya Chinthamani,**

"கருதியே கனமான கொடுமை செய்து
கணவனையே நிந்தனைதான் சொன்ன பேரும்
பருதியின்முன் மலசலத்தை விட்ட பேரும்
பரதேசியே ழைகளைப் பழிக்கின்றோர்க்கும்
குருதியே யிரைக்கின்ற காலந் தன்னில்
கூசாமல் புருஷசங்கை பண்ணினோர்க்கும்
கருதியே பரயோகம் விரும்பி னோர்க்கும்
சுருக்கிலே பெரும்பா டுற்பவிக்குந் தாமே

தானென்ற காரணிகள் மிகுக்கை யாலும்
சண்டாளக் கோபத்தின் சலிப்பினாலும்
ஊனென்ற மாமிசங்கள் பொசித்த லாலும்
உறக்கமின்றி விழித்தலா லூழித் தீயால்
பானென்ற பசியின்றிப் பொசிக்கை யாலும்
பாரமாஞ் சுமைவாங்கல் பகலுறக்கம்
கூனென்ற குறுக்கலாம் முடக்கித் தூங்கல்
குரூரமாம் பெரும்பாடு கொட்டுந்தானே.[9]

- Women those who abuse or show severe cruel activity to her husband.
- Women who void urine and faeces in front of sun
- Women who criticize sages and poor people
- Women who have sexual intercourse at the time of menstruation
- Women who indulge in excessive sexual intercourse
- Women with vigorous anger
- Women often taking non-vegetarian foods.
- Sleeplessness without rest
- Taking food without appetite
- Lifting heavy loads
- Daytime sleep
- Sleeping in flexed position.

These conditions will cause the disease, Perumbadu Rogam.

**Mega noi, Soothaga Nool and Arivaiyar Chinthamani,**

"கண்டாயோ பெரும்பாடு கலந்த மார்க்கம்
கருதிக் கேள் மின்னாளே நன்றாய் இன்னும்
கொண்ட படிகாரமுள்ள வகைகள் தின்றால்
கூறாக மாதவிடை காலம் தன்னில்
விண்டாலும் வாய்வு அது மிஞ்சினாலும்
விளங்கும் மாமிசம் அதிகம் புசித்ததாலும்
உண்டாலும் மந்தமதில் புசித்ததாலும்
உறக்கமது ஒழிந்த விதத்தாலும்.

ஆகுமே கடும் சுமடெடுப்பதாலும்
கதிப்பாக பகலுறக்கம் பகல் சம்போகம்
பாகு பெற குறுக்கதுதான் கூனிக் கொண்டு
பண்பாகவே உறங்கும் தன்மையாலும்

வாகு பெறவே அதிக புணர்ச்சியாலும்

வலுவாக மேகமது உற்பவித்து

தாகமுற சூடெழும்பி தளவாய் நீறி

தனி வயறும் கருக்குழியும் புண்ணுண்டாமே."[10]

- Excessive intake of spicy foods
- Increase of Vatha during menstrual period
- Increased intake of non-vegetarian foods
- Intake of food during indigestion
- Insomnia
- Lifting heavy weights
- Daytime sleep
- Sexual act during daytime
- Sleeping in flexed and Improper posture
- Increased sexual intellectual.

**Agathiyar Gunavagadam,**

" பாரேநீ பெரும்பாடு வரும் வகையைக் கேளாய்

பக்குவமாய் வருகின்ற கண்டமாலை

ஊரேநீ மூத்திர குண்டிக்காயின் ரோகம்

உத்தமனே பீலிகா ரோகந் தானும்

தேரேநீ நாட்பட்ட பாண்டு ரோகம்

தெளிவாக இரத்தரோகம் தன்னா லையா

சீரேநீ சினைப்பைக்கும் கருப்பைக்கு மப்பா

சிறப்பாக அதிகரத்த மேறுங்கானே.

காணுவாய் சூதகம் வெளியாகுமப்பா

கருப்பைதான் அழலைகொண்டு போவ தாலே

பூணுவாய் சம்போக மதிகத்தா லும்

பொல்லாத புத்துகளாற் கட்டியா லும்

பேணுவாய் பெரும்பா டுண்டா மென்று

பெலமாக தீதான் சொல்லுவாய் உலகத்தோர்க்கு

காணுவாய் அப்போது கருப்பை நின்று

கருவான ரத்தத்தான் வருகுந்தானே."[11]

According to the text Agathiyar Gunavagadam, Perumbadu occurs in association with the following diseases:

- Tubercular adenitis
- Renal Diseases
- Chronic Aneamia
- Pelvic Inflammatory Diseases
- Uterine congestion
- Excessive coitus
- Benign and Malignant Tumours

**T.V. Sambasivam pillai,**

- Perumbadu is an immoderate secretion of the menstrual discharge.
- Uterine blood vessels lose their strength, muscle fibers get congested leading to Menorrhagia.[12]

Anubhoga Vaidhya Deva Ragasiyam- Shthiriroga Nithanamum, Sigichchaiyum

- Intake of food which increases body heat.
- Excessive intake of food.
- Indigestion.
- Uterine congestion.
- Excessive coitus
- Climbing hills.
- Excess walking and excess sleep.
- Fasting.
- Loss of body weight.
- Lifting heavy weights

- Injury by sticks and rods
- Sleeping during Daytime[13].

**SOOTHAGAM UNDAGUM VITHAM**

In Mega Noi, Soothaga Nool mattrum Arivaiyar Chinthamani, the process of Menstrual Cycle is mentioned.

"திங்களுறு மங்கையர்கள் கெற்பாசயமதை
தாங்கியிரு சிவிகையுண்டு
சிவிகையிரு பக்கமும் வீசியே
நிற்குமதினின்றொரு குழல் நரம்பு
பங்கமறவேயெழும் அடிவயிறு யோனியும்
சுற்றிப் பிணைந்து கொண்டு
பகருமதிலொரு முனை இரத்தாசயமதைக்
கவ்விக் குவிந்திருக்கும்

இங்கிதமதாகவே மறுமுனையது
அரிவையர் கெற்பாசயம் புகுந்து
இனிதாயரவினுட வாயளவாகவே
மூவிரலசைந்து நிற்கும்
மங்களமதாயிந்த நாதக்குழல்
வழி ரத்தாசயத்தினின்று
மறுவகலவே காரிரத்தம் சுரந்தினி
கெற்பாசயததிலே தான்

நிதமுமிது தவறாது ஒரே துளிவிழும்
ஆறஞ்சதாம் நாளிலே
நேசமொரு குழல்வழி உருகியது வெளியிலே
பாயுமது யோனி வழியாய்

பதமாகவே சுகதேகியதுவாகிலொ
பூத்த முதல் மூன்று நாளும்
பகருதினி மோராற் கழஞ்சு நிறை பாயுமே
மேகமதினால் சூட்டினால்
இதமான வாயுவால் கிருமியின் ஏதுவால்
பூத்த பின் கணவனோடே
சேருவதினாலேயும் கடுநடைகளாலினி
சுமடு வெயில் தாக்குவதினால்

விதமான நாதமது கூடும் குறைந்திடும்
கெற்பமில்லாமலாகும்
விள்ளுமோராறு வகை வாயுவது
துதித்திடும் கேளு நீ ஒவ்வொன்றாய்[14].

**PERUMBADU – CLINICAL FEATURES**

**Mega noi, Soothaga Nool mattrum Arivaiyar Chinthamani**,

"கையுடன் காலுங் காந்துங் காத்திர முலர்ந்து வற்று
மையலாங் கலவி தன்னை மறுத்திடுங் கர்ப்பங் கேடாஞ்
செய்யநீர் போலுஞ் சற்றே சிவந்திடும் குருதிபோலும்
பெய்யுமே யாகில் மானே! பெரும்பாடென்றறிகுவீரே"[15]

- Burning sensation of upper and lower limbs
- Emaciation of Body
- Loss of libido
- Failure to conceive
- Watery or reddish discharge

**Aaviyalikum Amuthamurai Churukkam**,

"பார்த்திடவே மங்கையர்க் கிரத்த சூலை
பகருகிறே னடிவயிற்றில் பற்றி நிற்கும்
கோர்த்திடவே உதிரமது திரண்டு மேதான்
கொதிப்பெடுத்து மாதவிடாய்க் காலந் தன்னில்
சேர்த்திடவே சூதகமும் மிகுந்து காணும்
சிறுவழியாய்க் கருவழியும் புறண்டு ளைக்கும்
ஏர்த்துடனே தொடையிடுப்பு உளைச்ச லாகும்
இரத்தசூலைக் குணமிதுவே பாரு பாரே.(16)"

- Excessive menstrual bleeding
- Mild abdominal pain
- Pain in thighs and hip region.

**Agathiyar Gunavagadam,**

"இரத்த மொருக்கால் தகையாமல் லெனவே யோடுபோல்
வீழுந்திருக்கும் சிரத்தில் கனப்புமுண்டாகும் திதமாய் சிதகிறே விழரத்தம்
சாத்த ரத்த ரோகமெனச் சொல்லும் நல்ல வல்லரே.(17)"

- Excessive bleeding with clots
- Head ache
- Scattered blood.

**Mega noi, Soothaga Nool mattrum Arivaiyar Chinthamani**

"வெளிவாக இரத்த சூலை சொல்லக் கேளு
விரைவாக அடிவயிற்றில் இரத்தம்
தெளிவாக பூக்குமந்த காலம் தன்னில்
திட்டமாய் இரத்தமது அதிகம் பாயும்

களிவாக வயறதனில் நோவுண்டாகும்
கருவழிக்கும் வயறுபிரட்டும் கன நோவாகும்
அளிவாக இடுப்பு துடை அயர்ந்து போகும்
அறிகுவாய் இரத்த சூலையென்று செப்பே.[18]"

- Excessive menstruation
- Lower abdominal pain
- Pain in thighs and hip region.

**NOI ENN (CLASSIFICATION)**

In **Yugi vaithiya chinthamani-800,** about 4 types of Perumbadu diseases are described.

"உரை செய்த பெரும்பாடு நால தாகும்
உகந்துமே வாதத்தின் சிராவ மொன்று
புரை செய்த பித்தத்தின் சிராவ மொன்று
பேரான சேட்டுமத்தின் சிராவ மொன்று
துரை செய்த தொந்தமாஞ் சிராவ மொன்று
துகையெல்லாம் நாவிதச் சிராவ மாச்சு
கரைசெய்த விதனுடைய உற்பத்தி யெல்லாம்
கண்டபடி சொல்லவே கருதிடாயே" [19]

- VATHA PERUMBADU
- PITHA PERUMBADU
- KABHA PERUMBADU
- THRITHOSA PERUMBADU.

**PITHA PERUMBADU**

"ஆமென்ற வன்னத்தை இறங்கொட் டாது
அழுகின்ற மஞ்சள் நிறம் போல ஊற்றும்
வேமென்ற யோனியிலே வேக்கா டுண்டாம்
மேனியுமோ வெளுத்துமே ரத்தம் போகும்
காமென்ற கால்கையு மழற்ற லாகும்
கருகலாய்க் கட்டிபோ லுதிரம் வீழும்
தேமென்ற சிறுகடுப்பா மங்க மெல்லாம்
சீரிய தோர் பித்தத்தின் சிராவ மாமே. (20)"

- Loss of appetite
- Menstrual bleeding with slight yellowing color tinch
- Soreness of vagina
- Pale color of the body
- General weakness of limbs
- Menstrual bleeding with black coloured blood clots
- Body Pain

**Mega noi, Soothaga Nool mattrum Arivaiyar Chinthamani,**

**PITHA PERUMBADU**

"சொல்லுவேன் பித்தத்தின் பெரும்பாடென்றால்
சுடும் மஞ்சள் நிறம் ரெத்தம் வெறுக்கும் அன்னம்
சல்லியமாய் யோனியது வெந்து நீறும்
சாவாக உடல் வெளுக்கும் ரத்தம் வற்றும்
மெல்லவே கால் கையும் காந்தலுண்டாம்
மெய்யுருகி கட்டியதாய் இரத்தம் போகும்
இல்லையினி தேகமது உளையும் சற்று
இது பித்த பெரும்பாடென்று உரைக்கலாமே(21)"

- Pale coloured menstrual bleeding with yellowish tinch.
- Aversion of food
- Burning sensation on vagina
- Pale color of the skin due to decreased hemoglobin
- Burning sensation on palms and soles
- Menstrual bleeding with clots
- Pain all over the body.

**CLASSIFICATION OF OTHER PERUMBADU TYPES**

**Yugi Vaithiya Chinthamani,**

**VATHA PERUMBADU**

"கூடுமே தலைவலியு மேற்க டுப்பும்
கூறான முதுகிடுப்புக். குடைச்ச லுண்டாம்
வாடுமே தேகமெலாங் கருக்க லாகும்
மாதவிடாய் கரித்துமே மைந்தன் போலாம்
ஊடுமே வயிறூதி உளைச்ச லாகி
ஊற்றுமே செந் நிறமுங் கருக லாகத்
தேடுமே துற்கந்தஞ் சேர வொட்டா
செகமறிய வாதத்தின் சிராவ மாமே[22]"

- Head ache
- Pain in lumbar and hip region
- Abdominal distension
- Body pain
- Dark coloured menstrual bleeding
- Menstrual bleeding with foul smell.

**KABHA PERUMBADU**

"ஆகுமே வெள்ளை நிறமாக ஊற்றும்
அலியான நாற்றந்தான் மிகவுண் டாகும்
வேகுமே வுடம்பெங்கும் விபூதி பூக்கும்
வெந்தழலா யுடம்பெங்கும் எரிச்ச லாகும்
பாகுமே படபடப்பு மூச்சு முண்டாகும்
பாரமாங் கோழையொடு மயக்க மாகும்
தேகுமே யடிக்கடிக்கு மயக்க மாகும்
சேட்டுமத்தின் சிராவ மென்றே செப்பாமே[23]"

- Pale coloured menstrual bleeding
- Menstrual bleeding with Foul smell
- Salty appearance on the body
- Burning sensation on all over the body
- Palpitation
- Cough with fatigue

**THRITHOSHA PERUMBADU**

"செப்பவே கருநல்லாய்ச் சிவப்பு மாகும்
சேர்ந்ததிலே கட்டியாய்க் கருப்பாய் வீழும்
உப்பவே வயிறது முல்லைச்ச லாகும்
ஊசலா நாற்றமுட னொழுக்க மாகும்
நம்பவே மஞ்சள் நிற நயப்பு மாகும்
நாணியே தலைதானு நடுக்க லாகும்
துப்பவே வாய் நீரு மிகவே வூற்றும்
தொந்தமாம் பெரும்பாடு சூட்டினோமே[24]"

- Dark brown colored menstrual bleeding with clots
- Abdominal distension with pain
- Menstrual bleeding with foul smell
- Tremors of the head
- Increased salivation.

**Mega noi, Soothaga Nool and Arivaiyar Chinthamani**,

**VATHA PERUMBADU**

"பாடாமல் வாதத்தின் பெரும்பாடுற்றால்

பண்பாக தலைவலிக்கும் தேகம் நோகும்

நாடாமல் முதுகொடு இடுப்பு தானும்

நொந்து மிக வருத்தமிகும் உளைவுண்டாகும்

கூடாகவுடல் மெலியும் கருகும் தேகம்

கொள்ளும் மாதவிடாய் காலம் வயறு நோகும்

ஊடாகவே உருளும் குழந்தை போலே

உறு பெருமல் செந்நிறமாய் இரத்தம் நாறும்[25]"

- Head ache
- Pain in all over the body
- Pain in lumbar and hip region
- Loss of weight
- Lower abdomen pain during menstruation
- Dark red colored menstrual bleeding with foul smell.

**KABHA PERUMBADU**

"போமே சேர்ப்பனத்தின் பெரும்பாடென்றால்

பொருந்து வெள்ளை நிறமாக ரத்தம் விழும்

வாகுபெறவே நாறும் தேகம் தானும்

வளர் நீறும் போலெரியும் அழலும் தேகம்

தாகமுறும் படபடத்து மூச்சு வாங்கும்

தனித்த கபமிருமலொடு வேவுண்டாகும்

பாகுபெற அடிக்கடி மயக்கமுண்டாகும்

பகருவேன் சேர்ப்பனத்தின் பெரும் பாடென்றே[26]"

- Pale colored menstrual bleeding
- Menstruation with foul smell
- Burning sensation on whole body
- Increased thirst
- Palpitation
- Dyspnea
- Cough
- Fatigue.

**THRITHOSHA PERUMBADU**

"உண்டான திரிதோஷ பெரும்பாடென்றால்

உள்ளபடி கல்லுப் போல் கட்டியாகும்

விண்டு கறுப்ப்பாய் சிகப்பாய் மஞ்சள் போலும்

விதம் விதமாய் இரத்தமது நிறம் மாறிப் போம்

கண்டாலும் வயறுளையும் நாற்றம் மீறும்

கடிதான தலை நடுக்கம் வாய் நீரூறும்

மிண்டாத திரிதோஷ பெரும்பாடின்

மிகு பெருமையுள்ளபடி செப்பினேனே[27]"

- Black, red or yellow coloured menstrual bleeding
- Abdominal Distension
- Foul smell Menstrual bleeding
- Tremors of the head
- Increased salivation.

**SAATHIYAM AND ASAATHIYAM (CURABLE AND INCURABLE)**

**Yugi Vaithiya Chinthamani,**

"சூடியதோ ரசாத்தியத்தைச் சொல்லக் கேளாய்
சொல்லும்சேட்ப பெரும்பாடு தொந்தசசி ராவம்
பூட்டினதோ ரிரண்டும் பிழைக் கொட் டாது
புகழான சாத்தியத்தை விளம்பக் கேளாய்
வாட்டினதோர் வாதத்தின் பெரும்பா டோடு
வகையான பித்தத்தின் சிராவந்த் தானும்
தீட்டினதோர் மருந்துக்குச் செயமு மாகும்
செப்பினதோர் நன்னூலைத் தெளிந்து பாரே[28]"

- Vatha perumbadu and pitha perumbadu are curable.
- Kabha perumbadu and thrithosha perumbadu are incurable.

**Mega noi, Soothaga Nool and Arivaiyar Chinthamani**

"சாற்றுவேன் வாதத்தின் பெரும்பாடொன்று
சலியாமல் பித்த பெரும்பாடு தானும்
போற்றியதோர் சேர்ப்ப பெரும்பாடொன்று
பொருந்து திரிதோஷ பெரும்பாடு நாலாம்
ஆற்றியதோர் வாத பெரும் பாடினோடு
அதிகமாய் பித்த பெரும்பாடு தீரும்
மாற்றியதோர் சேர்ப்ப பெரும் பாடினோடு
மருவு திரிதோஷ பெரும்பாடு அசாத்தியம்[29]"

- Vatha perumbadu and pitha perumbadu are curable.
- Kabha perumbadu and thrithosha perumbadu are incurable.

**THOADA KURIKUNANGAL (SEQUELAE OF COMPLICATIONS)**

"தேகத்தூறு மனலும் தீதாமதி லெரிச்சல்
வேகப்பெரும்பாடு வெண்ணிறமாய்ப்—போகவதில்
நாற்றமேல் மூச்சு நவிலக்கப மயக்கம்
தோற்றவுடல் சாயுஞ் சொல்[30]"

- Burning sensation on all over the body
- White coloured menstrual bleeding
- Menstrual bleeding with Foul smell
- Dyspnea
- Giddiness

**MUKKUTTRA VERUPAADUGAL (PATHOLOGY)**

According to Siddha System, Body is constituted by 96 thathuvas. Normal structural and physiological state of the body is maintained by equilibrium with Mukkuttram and seven Udarkattukal.

As the Udarkattukal are affected by the extrinsic and intrinsic factors, there is deterioration in the structural and functional status of the body. When the causative factor affects Udarkattukal and Mukkuttram, it results in incoordination of functions. Thereby the diseases manifest and expose its clinical features.

In Perumbadu, clinical condition is due to the imbalance of Pitham. Pitham is deranged primarily and later it deranges Vatha and the derangement of Pitha- Vatha leads to the derangement of Abaanan which in turn cause the disease. The pathogenesis of the disease depends upon the affected Pitha and Vatha.

**DIAGNOSIS OF PERUMBADU BASED ON SIDDHA SYSTEM:**

According to Siddha System, the diagnosis of a disease is reached by the Envagai thervu, Uyirthathukkal and Udal thathukkal.

**ENVAGAI THERVU OR PINIARIMURAIMAI**

The disease Perumbadu Rogam was diagnosed by the following methods:

- Poriyaal arithal
- Pulanaal arithal
- Vinaathal
- Uyir thathukkal
- Udal thathukkal
- Envagai thervu

**PORIAL ARITHAL** – understanding by the fire organs of perception

- Nose
- Tongue
- Eye
- Skin
- Ear

**PULANAAL ARITHAL** – understanding by the sense objects

- Odour (smell)
- Taste
- Vision
- Touch (tactile)
- Sound (hearing)

**VINAATHAL (**Interrogation)

Patient name, age, occupation, address, socio-economic status, family history, diet habits prone for any allergens, period of suffering, history of previous episode, history of treatment, habits etc are noted through interrogation.

**UYIRTHATHUKAL**

Panchaboothams are manifested in the body as three vital forces.

- Vaatham
- Pittham
- Kabham

**VAATHAM :**

It is the combination of vaayu and aakasa boothams. It is responsible for all the movements of the body. It helps in the uniform functioning of seven Udal thathukkal

**The sites of vaatham:**

Umblicus, rectum, faecal matters, abdomen, anus, bones, hip joint, naval, plexus, joints, hair follicles and muscles.

**Vaatham has ten types:**

1. **Praanan** (uyirkaal) :
   This controls knowledge, mind and five sense organs, which are useful for breathing and digestion.
2. **Abaanan** (Keezh nokku kaal) :
   This is responsible for all downward movements such as passing urine, stools, semen, menstrual flow etc.
3. **Samaanan** (Nadukkaal) :
   This aids in proper digestion.
4. **Viyaanan** (paravukaal).
   This is responsible for all movements of all parts of the body.
5. **Uthaanan** (Mel Nokkukaal)
   Responsible of all upward visceral movements, such as vomiting, eructation and nausea.
6. **Naagan** :
   Responsible for opening and closing the eyes.
7. **Koorman** :
   Responsible for vision and yawning.
8. **Kirukaran** :
   Responsible for salivation, nasal secretion and appetite.
9. **Devathatthan** :
   Resposible for Laziness, sleeping and anger.

**10.Thananjeyan** :

Produces bloating of the body after death. It escapes on the third day after death bursting out of the cranium.

**In perumbadu Rogam**

| | | |
|---|---|---|
| Praanan | - | Affected (Dyspnoea, breathlessness) |
| Abaanan | - | Affected (Excessive, prolonged Menstruation) |
| Samaanan | - | Affected (loss of appetite) |
| Viyaanan | - | Affected (body pain) |
| Uthaanan | - | Affected (Nausea, vomiting) |
| Naagan | - | Normal |
| Koorman | - | Normal |
| Kirukaran | - | Normal |
| Devathatthan | - | Affected (Tiredness) |

**PITHAM :**

It is the manifestation of 'THEE' bootham in the body. It is the metabolic thermal life force of the body. It carries out digestion, absorption, metabolism, colouring of blood etc.

**The sites of Pittham:**

Praana vaayu, urinary bladder, moolaakkini, heart, umblical region, abdomen, stomach, sweat, saliva, blood, eyes and skin.

**Pitham has 5 types**

**1. Analagam** : It promotes appetite and helps in digestion.
**2. Ranjagam** : It gives colour to the blood.
**3. Praasagam** : It gives complexion to the skin.
**4. Aalosagam** : It brightens the eyes.
**5. Saathagam** : It controls the whole body. It has the property to fulfil all the activities which the mind desires.

**In Perumbadu Rogam**

- Anal pittham - Affected (Loss of appetite)
- Ranjaga Pittham - Affected (low Hb level)
- Saathaga Pittham - Affected (General malaise)
- Aalosaga Pittham - Normal
- Praasaga Pittham - Affected(Pallor of skin)

**KABHAM :**

It has Neer and Mann boothams. It is responsible for co-ordination and defence mechanisms of the body.

**The sites of Kabham :**

Samaana vaayu, semen, suzhumunai, blood, phlegm, bone marrow, nose, chest, nerve, bone, brain, eyes and joints.

**Kabham has 5 types**

**1**. **Avalambagam** : Lies in the lungs, controls the heart and other kabhams.

**2. Kilethagam** : Lies in the stomach, makes the food moist, soft and helps in digestion.

**3**. **Pothagam** : Responsible for identifying taste.

**4. Tharpagam** : Present in the head and responsible for the coolness of both eyes.

**5**. **Santhigam** : Responsible for lubrication and free movements of joints. It is situated in the joints.

**In Perumbadu Rogam**

- Avalambagam - Normal
- Kilethagam - Affected (loss of appetite)
- Pothagam - Normal
- Tharpagam - Normal
- Santhigam - Affected(Low back pain)

## EZHU UDAL THATHUKKAL

Normal functions :

**Saaram**

It gives the good spirit to body and mind.

**Senneer**

Blood imparts colour to the body and nourishes the muscle responsible for the ability, intellect of the individual.

**Oon**

It gives shape to the body according to the requirements for the physical activity,

nourishes bone.

**Kozhuppu**

It helps in lubrication of different organs.

**Enbu**

Supports and responsible for posture and movements of the body.

**Moolai**

It fills the bony cavity and gives nourishment.

**Suronitham**

It is responsible for the reproduction.

**In Perumbadu Rogam**

| | | |
|---|---|---|
| Saaram | - | Affected (Tiredness) |
| Senneer | - | Affected (pallor) |
| Oon | - | Normal |
| Kozhuppu | - | Normal |
| Enbu | - | Affected (low back pain) |
| Moolai | - | Normal |
| Suronitham | - | Affected (Excessive or prolonged menstruation) |

## ENVAGAI THERVU

"மெய்க்குறி நிறந்தொனி விழிநாவிருமலம் கைக்குறி"[31]

Envagai thervugal can be done by the following,

- Naa
- Niram
- Mozhi
- Vizhi
- Malam
- Moothiram
- Naadi
- Sparisam

**NAA (Tongue)**

- Colour
- Coating
- Taste
- Dryness
- Ulceration

In Perumbadu Rogam, tongue is not affected but non-specific and unrelated symptoms such as dryness and coating may be seen in some cases.

**NIRAM (Colour)**

- Colour of the Skin

In Perumbadu Rogam, Paleness of skin may be seen due to excessive menstruation.

**MOZHI (Voice)**

- Articulation or speech

In Perumbadu Rogam, low pitched voice may be noted due to severe pain in lower abdomen.

**VIZHI (Eyes)**

- Niram (Pallor, icterus)

In Perumbadu Rogam, pallor may be noted.

**MALAM (Motion)**

- Niram – Colour
- Irugal, Ilagal- consistency
- Manam – Odour

In Perumbadu Rogam, constipation may be seen.

**MOOTHIRAM (Urine)**

**Rules for the Collection of Sample urine:**

"அருந்துமாறிரதமும் அவிரோதமதாய்
அஃகல் அலர்தல் அகாலவூன் தவிர்ந்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிக்கலசத் தாவியே காது பெய்
தொருமுகூர்த்தக் கலைக்குட்படு நீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே[32]"

The patient must take well cooked food in the previous day. The intake must be proportionate to the degree of his appetite. Food intake should be taken, at appropriate time. The patient must have sound sleep on the previous night. The urine is collected on the dawn of the next day in a glass container and closed immediately to prevent contamination. This specimen must be examined with in one and half hours. This procedure should be followed strictly to get accurate observation of Neerkuri and Neikuri.

**NEERKURI**

The collected urine should be noted for the following 5 characters,

- Niram - Colour
- Edai - Specific gravity
- Nurai - Frothy
- Manam - Odour
- Enjal - Deposit

In Perumbadu, the urine is clear without froth.

**NEIKURI**

" நிறக்குறிக் குரைத்த நிருமாண நீரிற்
சிறக்க வெண்ணெய்யோர் சிறுதுளி நடுவிடுத்
தென்றுறத் திறந்தொலி ஏகாதமைத்ததி
நின்றதிவலை போம் நெறிவிழியறிவும்
சென்றது புகலுஞ் செய்தியை யுணரே[33]"

This stanza describes the speciality of Neikuri. Of all diagnostic methods, Neikuri reveals the true nature of the disease and prevents wrong diagnosis.

Snake like appearance-Vatham
Ring like appearance-Pitham
Pearl like appearance-Kabham

**NAADI (PULSE)**

நாடி மூன்றையும் நாடிடுங் காலை
நடுவிரல் நாடியை நாடியே கணிப்பான்
நற்றவர்க்குருவென நவிலு மறையே[34].

Naadi is a Unique Siddha Pulse reading method and it should be felt and not read. Different gaits of Vazhi , Azhal, Iyam like branching, jumping, mixing, rotating and compression can be identified.

**NAADI INDICATING PERUMBADU ROGAM**

In Perumbadu Rogam, Pitha naadi and vathathil ushna naadi was diagnosed

"உறுதியுள்ள பித்தமது தோன்றில் வெப்பு
உஷ்ணவாயு வத்திசுர மதிசா ரங்கள்
மறதியுடன் கிறுகிறுப்பு பயித்திய ரோகம்
வளர்சோகை யழலெரிவு காந்தல் கைப்பு
இருதயத்தில் கலக்கமது மறப்பு தாகம்
எழுங்கனவு மேயனைவு மயக்க மூர்ச்சை
சிறிதுபெரும் பாடுரத்தம் பிரமே கங்கள்
சேர்ந்துமிகு பிணிபலவுஞ் சிறக்குந் தானே[35]

"சிறப்பான வாதத்தி லுட்டிணந் தானே
சேர்ந்திடுகி லதிசார முளைச்சல் வாயு
உரைப்பான பொருமலொடு அக்கினி மந்தம்
உள்ளாகும் நீர்ச்சிறுப்பு பிரமே கங்கள்
பிறப்பாடு மதகரிநீர் கரப்பான் ரத்தம்
பிரமேகம் பெரும்பாடு புறநீர்க் கோவை
அறப்பான வாயுசூலை சேத்தும ரோகம்
ஆனபல பிணிகளுமே வந்தடருந் தானே[36]"

**MARUTHUVAM:**

In Siddha science, the treatment is not only for removal of the disease, but for the prevention and improving the body condition after the removal of the disease.

This is classified as

- Kappu (Prevention)
- Neekam (Treatment)
- Niraivu (Restoration )

**KAAPU:**

It is the method of preventing the disease. Prevention Siddha principles based mainly on prevention as mentioned in "Theraiyar pini Annuga vithi" by Theraiyar.

In "THERAIYAR PINIANUGAAVITHI" certain traditional principles of prevention are mentioned. In addition "SARABENDHIRAR" prescribes a few rules to be followed at the time of the menstruation.

**DONT'S**

- Avoid anchanam for the eyes
- Avoid purgatives
- Avoid heavy works
- Avoid activities like jumping, too much of crying and laughing
- Avoid emotional stress
- Avoid tobacco chewing

- Avoid strong tea and coffee
- Avoid fast food and spicy items
- Avoid excess salt, spices, sweets and fat foodstuffs

**DO'S**

- Advice to take plenty of fibre rich foods like fruits, greens, nuts and leafy vegetables.
- Advice to take Iron enriched greens, vegetables and cereals. Iron containing vegetables and fruit supplementation (100mg/day) prevents anaemia.
- Vitamin C enriched diet which ensures Iron absorption and capillary constriction.
- Daily consumption of dates.
- Salt restricted diet.
- Reducing caffeine and sugar.
- Hip bath – Hot water hip bath as routine practice should be taken for 10mts.
- Gentle exercises such as deep breathing exercises, progressive muscle relaxation, range-of-motion exercises to keep the joints mobile and slow relaxed walking promotes good oxygenation and circulation and can even help to increase energy.
- Hygiene should be advised during menstruation.

Prevention of disease is also achieved by following proper diet and good habits. Proper diet not only means the intake of nutritious diet but also abstinence from edible substances which are injurious to health.

**NEEKAM**

Agasthiyar kuzhambu – 100 mg with chukka kashayam should be administered as single dose at early morning before commencement of treatment.

For the disease, Maampisin Chooranam -2 gms thrice a day with ghee for Day 1 to 15 days of menstruation for 3 consecutive cycles is administrated.

**Pathiya pathartham:**

Proper dietic regimen enhances the effect, bioavailability of the medicine and helps to maintain good health. This form of medical advice in Siddha is termed as Pthiyam. If Pathiyam is not followed properly, certain foods may become incompatible and antagonise the effect of medicine and produce harmful effects to the body.

**Abathiya pathartham:**

"கொள்ளு காடி குமட்டிக்காய் பன்றி கொக்குடனே
முள்ளிற் பெரிய பாகற்காய் முதிரும் அவரை பயற்றங்கால்
பள்ளத் தெளுந்த மடற்சேம்பு படரும் வள்ளி பாலயிவை
எள்ளத் தனைதான் தின்பீரேல் எல்லா மருந்தும்
இழந்தீரே[37]"

கொள்ளு, காடி, குமட்டிக்காய், பன்றி இறைச்சி, கொக்கு, பாகற்காய், அவரைக்காய், உளுந்து, சேம்பு, எள்ளு முதலியவற்றை தவிர்க்க வேண்டும்.

**Itchaa pathiyam:**

"கடுகு நற்றிலத் தெண்ணெய் கூழ்பாண்டங்கள் கடலை
வடுவ தாகிய தெங்குமா வருக்கை நற்காயம்
மடிவி லாதவெள் ளுள்ளி கொள்புகையிலை மதுபெண்
இடறு பாகலோ டகத்தி நீக்கிடலிச் சாபத்தியம்[38]"

கடுகு, நல்லெண்ணெய், கடலை, தேங்காய், மா, பலா, பெருங்காயம், பூண்டு, கொள்ளு, புகையிலை, மது, பெண்போகம், பாகல், அகத்தி முதலியவற்றை தவிர்க்க வேண்டும்.

## YOGASANA

Yoga helps us directly to hold physical forces in balance indirectly to develop mental and spiritual powers. Yoga practice tone up the pelvic organs and muscles and promote good circulation. Minor structural and functional defects of the body can be rectified by the systemic practice of Yogasanas and Pranayamas

Women should keep in mind that they should not do asanas during their monthly menstrual period. After the period ends, asanas can be practiced and it will give a lot of benefits.

The following aasanas are advised in menorrhagia:

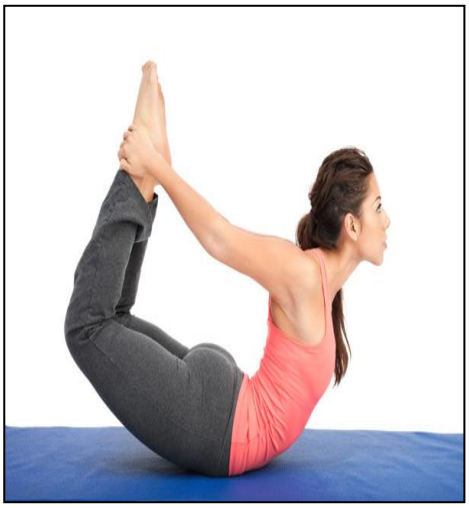
- Trikonasana
- Vajrasana
- Halasana
- Patchimothasana
- Garudasana
- Savasana
- Baddhakonasana
- Sarvagasana [39]

## YOGASANA

**TRIKONASANA**

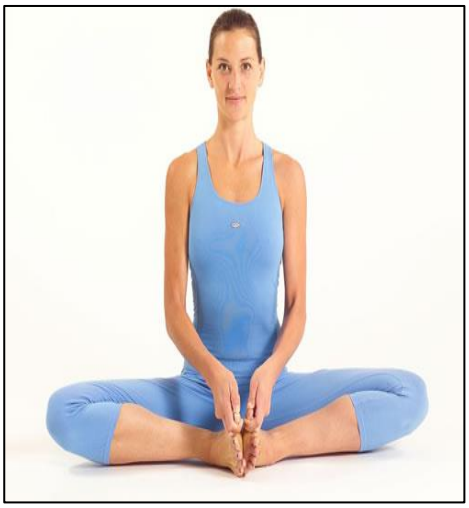
**VAJRASANA**

**HALASANA**



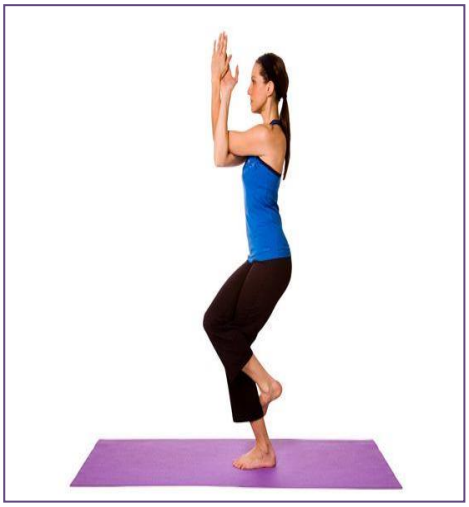
**PATCHIMOTHASANA**

**SARVANGASANA**



**BADDHAKONASANA**

**SAVASANA**



**GARUDASANA**

**NIRAIVU (RESTORATION):**

Physical, Psychological, social and economic rehabilitation of individual is known as Niraivu.

In Pitha Perumbadu, Azhal kutram is deranged and causes impairment of dasavayu which in turn affect the seven Udal thathukkal.

The line of treatment aims at bringing back the affected thaathus to normal by the administration of internal medicine MAAMPISIN CHOORANAM[40].

Finally assurance of the patient gives her a moral boost thereby speeding up the recovery.

# MODERN ASPECT

# MODERN ASPECT

## FEMALE REPRODUCTIVE SYTEM

The female reproductive system consists of internal and external genitalia. The main functions of female reproductive system are

- Production of sex hormones
- Production of functioning gametes [ova]
- Support & protection of developing embryo

### EXTERNAL GENITALIA

The external female genitalia are referred to as vulva. It consists of the following structures namely,

- Mons pubis
- Labia majora
- Labia minora
- Clitoris
- Urinary Meatus (External Urethral Orifice)
- Hymen
- Perineum

The vestibule is the space into which the vagina and urethra open. The urethra opens just anterior to the vagina.

The vestibule is bordered by a pair of thin, longitudinal skin folds called the labia minora.

Lateral to the labia minora two prominent rounded folds of skin called the labia majora.

The two labia majora unite anteriorly in an elevation of tissue over the pubic symphysis called the mons pubis. The lateral surface of the labia majora and the surface of the mons pubis are covered with coarse hair.

The medial surface of the labia majora are covered with numerous sebaceous and sweat glands. The space between the labia majora is called the pudendal cleft.

A small erectile structure is called the clitoris is located in the anterior margin of the vestibule. The two labia minora unite over the clitoris to form a fold of skin called the prepuce [41].

The perineum is bounded above by the inferior surface of the pelvic floor, below by the skin between the buttocks and thighs, laterally by the ischiopubic rami, ischial tuberosities and sacrotuberous ligaments and posteriorly by the coccyx[42].

**INTERNAL GENITALIA**

The internal reproductive organs situated in the pelvis between the bladder and rectum. They are held in space within the pelvis by a group of ligaments.

The internal genitalia includes

- Vagina
- Cervix
- Uterus
- Fallopian Tubes
- Ovaries

**VAGINA**

- The vagina is a muscular, hollow tube that extends from the vaginal opening to the cervix of the uterus. It also is known as the birth canal.
- It is a fibro muscular tube of about 10 cm long.
- It is female organ of copulation and allows menstrual flow and child birth.
- In young females it is covered by a thin mucous membrane called hymen[43].

**CERVIX**

- The cervix is the lower, narrow portion of the uterus where it joins with the top end of the vagina.
- During menstruation, the cervix stretches open slightly to allow the endometrium to be shed.
- During childbirth, contractions of the uterus will dilate the cervix up to 10 cm in diameter to allow the child to pass through [44].

**UTERUS**

- The uterus is a hollow, pear-shaped organ which is divided into parts namely Cervix, which is the lower part that opens into the vagina, and the main body of the uterus, called the corpus.
- The uterine wall is composed of three layers,
- Outer serous layer or perimetrium,
- Middle muscular layer or myometrium,
- Innermost endometrium.
- The endometrium consists of simple columnar epithelial cells with underlying connective tissue layer. The superficial part of endometrium is sloughed down during menstruation.

**POSITION OF UTERUS**

- Its normal position is anteversion and anteflexion. The uterus usually inclines to the right (dextrorotataion) so that the cervix is directed to the left (levorotation) and comes in close relation with the left ureter.

**MEASUREMENT OF UTERUS**

- The uterus measures about 8cm long, 5cm wide at the fundus and its walls are about 1.25cm thick. Its weight varies from 50-80 gm.

**PARTS OF THE UTERUS**

- Body or corpus
- Isthmus
- Cervix[45]

**FALLOPIAN TUBES**

- There are two uterine tubes also called uterine tubes or oviducts.
- One uterine tube is associated with each ovary.
- The uterine tubes extend from the ovaries to the uterus. They open pear the ovary to receive the oocyte and the opening is surrounded by long thin processes called fimbriae.

- As soon as oocyte is ovulated, it comes into contact with the surface of the fimbriae and the cilia on the fimbrial surface sweep the oocyte into the uterine tube.
- Fertilization usually occurs in the uterine tube near the ovary [46].

**OVARIES**

- The two ovaries are small oval shaped organs attached to ligaments that suspend them in the pelvic cavity and from the ligament of the uterus.
- The suspensory ligament extends from each ovary to the lateral body wall and the ovarian ligament attaches the ovary to the uterus.
- A layer of visceral peritoneum called tunica albuginea covers the ovary. The outer cortex of the ovary is made up of dense connective tissue containing ovarian follicles. Each of the ovarian follicles contains an oocyte the female germ cell [47].

**PHYSIOLOGY OF MENSTRUAL CYCLE**

**DEFINITION**

Menstruation is the visible manifestation of cyclic physiologic uterine bleeding due to shedding of the endometrium following invisible interplay of hormones mainly through hypothalamo-pituitary-ovarian axis.

For the menstruation to occur, the axis must be actively coordinated, endometrium must be responsive to the ovarian hormones (oestrogen and progesterone) and the outflow tract must be patent.

**DURATION OF MENSTRUAL CYCLE**

The period extending from the beginning of a period to the beginning of the next one is called menstrual cycle. The first menstruation (menarche) occurs between 11-15 years with a mean of 13 years. It is more closely related to bone age than to chronological age. For the past couple of decades, the age of menarche is gradually declining with improvement of nutrition and environmental condition.

Once the menstruation starts, it continues cyclically at intervals of 21-35 days with a mean of 28 days.

Physiologically, it is kept in abeyance due to pregnancy and lactation. Ultimately, it ceases between the age 45-50 when menopause sets in.

The duration of menstruation is about 4-5 days and the amount of blood loss is estimated to be 20-80ml with an average of 35ml. Nearly 70% of total menstrual blood loss occurs in the first 2 days.

**CONTENTS OF MENSTRUAL DISCHARGE**

The menstrual discharge consists mainly of dark altered blood, mucus, vaginal epithelial cells and fragments of endometrium, prostaglandins, enzymes and bacteria [(48)].

**MENSTRUAL SYMPTOMS**

In majority, apart from bleeding from vagina there is no symptom. Initially, it begins as pink discharge but on day 2 and 3 it becomes dark red.

In teenagers or nulliparous, there may be associated tolerable colicky pain at the beginning due to uterine contraction.

If the pain is of sufficient magnitude so as to incapacitate the day-today activities, it is called dysmenorrhoea.

There may be premonitory symptoms such as

- Pelvic discomfort
- Backache
- Fullness of the breasts or mastalgia
- Headache or depression
- Constipation or diarrhoea
- Appetite changes or food carvings
- Irritability or mood swings

These symptoms are predominant and grouped into a syndrome called Premenstrual syndrome [(49)].

**CHANGES DURING MENSTRUAL CYCLE**

During each menstrual cycle, series of changes occur in ovary, uterus, vagina and cervix.

**OVARIAN CHANGES DURING MENSTRUAL CYCLE**

It occurs in two phases, which includes

- Follicular phase
- Luteal phase

**UTERINE CHANGES DURING MENSTRUAL CYCLE**

Along with ovarian changes, uterine changes also occur simultaneously. This changes in uterus takes place in three phases which includes

- Menstrual phase
- Proliferative phase
- Secretory phase

**CHANGES IN VAGINA AND CERVIX DURING MENSTRUAL CYCLE**

- Proliferative phase
- Secretory phase[50]

**PHASES OF MENSTRUAL CYCLE**

The day count for menstrual cycle begins on the first day of menstruation when blood starts to come out of the vagina. In this section, the length of menstrual cycle has been assumed to be 28 days (which is the average among women). The entire duration of a menstrual cycle can be divided into four main phases:

1. Menstrual phase (From day 1 to 5)
2. Follicular phase (From day 1 to 13)
3. Ovulation phase (Day 14)
4. Luteal phase (From day 15 to 28)

**MENSTRUAL PHASE (day 1-5)**

Menstrual phase begins on the first day of menstruation and lasts till the 5th day of the menstrual cycle.

The following events occur during this phase:

- The uterus sheds its inner lining of soft tissue and blood vessels which exits the body from the vagina in the form of menstrual fluid.
- Blood loss of 10 ml to 80 ml is considered normal.
- This phase is also known as destructive phase or phase of bleeding.
- During this phase, the uterus sheds its inner lining of soft tissue and blood vessels which exits the body from the vagina in the form of menstrual fluid.

**FOLLICULAR PHASE (day 1-13)**

This phase also begins on the first day of menstruation, but it lasts till the 13th day of the menstrual cycle. This phase is also known as preovulatory phase or proliferative phase or oestrogen phase. The following events occur during this phase:

- The pituitary gland secretes a hormone that stimulates the egg cells in the ovaries to grow.
- One of these egg cells begins to mature in a sac-like-structure called follicle. It takes 13 days for the egg cell to reach maturity.
- While the egg cell matures, its follicle secretes a hormone that stimulates the uterus to develop a lining of blood vessels and soft tissue called endometrium.

**OVULATION PHASE (day 14)**

On the 14th day of the cycle, the pituitary gland secretes a hormone that causes the ovary to release the matured egg cell. The released egg cell is swept into the fallopian tube by the cilia of the fimbriae. Fimbriae are finger like projections located at the end of the fallopian tube close to the ovaries and cilia are slender hair like projections on each Fimbria.

**LUTEAL PHASE (day 15-28)**

This phase begins on the 15th day and lasts till the end of the cycle. This phase is also known as secretory phase. The following events occur during this phase:

- The egg cell released during the ovulation phase stays in the fallopian tube for 24 hours.
- If a sperm cell does not impregnate the egg cell within that time, the egg cell disintegrates.

- The hormone that causes the uterus to retain its endometrium gets used up by the end of the menstrual cycle. This causes the menstrual phase of the next cycle to begin [51].

**HORMONES REGULATING THE CYCLE:**

A normal menstrual cycle depends on cyclical ovarian steroid secretions which in turn are controlled by the pituitary and the hypothalamus and to some extent by the thyroid and adrenal glands. So the hypothalamo-pituitary-ovarian axis is important. The following hormones play the major role,

- Gonadotropin releasing hormone (GnRH)
- Follicle stimulating hormone (FSH)
- Luteinising hormone (LH)
- Oestrogen
- Progesterone.

**GONADOTROPIN RELEASING HORMONE (GnRH):**

Gonadotropin releasing hormone is secreted by the hypothalamus which modulates the neural control of FSH and LH by the anterior pituitary. GnRH is released in a pulsatile manner. In preovulatory phase, it pulses every 60 minutes but slows down in luteal phase to one in 3 hours. GnRH is continuous in males but pulsatile in females. The hypothalamus is controlled by higher cortical centers (temporal lobe). Emotional upsets stimulate or depress the H-P-O axis and disturb the menstrual cycles.

**ANTERIOR PITUITARY HORMONE**

**FOLLICLE STIMULATING HORMONE (FSH)**

It is secreted by the beta cells of anterior pituitary gland. FSH controls the ripening of the primordial follicles and in combination with the luteinizing hormone activates the secretion of oestrogen. Its action starts after cease of menstruation and reaches the peak by 7th day and then declines to disappear around 18th day. Another small peak occurs in the premenstrual phase. Low FSH causes defective folliculogenesis and short or defective corpus luteal phase.

**LUTEINIZING HORMONE (LH)**

It is secreted by the beta cells of anterior pituitary gland. In combination with FSH it activates the secretion of oestrogen.

It brings about maturation of the ovum and causes ovulation.

LH stimulates the completion of the reduction division of the oocyte. Following ovulation it produces luteinization of the granulosa and the theca cells and initiates progesterone secretion.

The LH surge precedes ovulation by 24 to 36 hours.

**OVARIAN HORMONES**

**OESTROGEN**

The main sources of oestrogen are the theca end granulosa cells of the graafian follicles and corpus luteum, while the adrenal cortex is the secondary source.

Its level rises 6 to 7 days before ovulation and reaches the peak 2 days before ovulation and then declines.

It increases uterine vascularity and regenerates the endometrium after menstruation and is responsible for the proliferative hyperplasia of the endometrium.

**PROGESTERONE**

The corpus luteum is the main source of progesterone. The level rises after ovulation and reaches peak at mid luteal phase. With the degeneration of the corpus luteum its level falls and brings about menstruation.

If pregnancy occurs the corpus luteum continues to enlarge and secrete progesterone.

The high level of the hormone prevents menstruation and leads to amenorrhoea of pregnancy [(52)].

## MENORRHAGIA

### SYNONYM

Hyper-menorrhea

Menostaxis

### DEFINITION

Menorrhagia is defined as cyclic bleeding at normal intervals. The bleeding is either excessive in amount (>80ml) or duration or both. The term Menostaxis is often used to denote prolonged bleeding.

### CAUSES

Menorrhagia has some underlying pathology- organic or functional.

### ORGANIC CAUSES

- Pelvic
- Systemic
- Endocrinal
- Blood dyscrasias
- Emotional upset

### PELVIC PATHOLOGY

Due to congestion, increased surface area or hyperplasia of the endometrium.

- Fibroid uterus
- Fibroid polyp
- Adenomyosis
- Chocolate cyst
- PCOD
- Pelvic endometriosis
- IUCD
- Chronic tubo-ovarian mass
- Tubercular endometritis (early cases)
- Pelvic inflammatory diseases
- Retroverted uterus – due to congestion
- Granulosa cell tumour of the ovary

**SYSTEMIC CAUSES**

- Congestive cardiac failure
- Severe hypertension

**ENDOCRINAL CAUSES**

- Hypothyroidism
- Initial stages of Hyperthyroidism

**BLOOD DYSCRASIAS**

- Idiopathic thrombocytopenic purpura
- Leukaemia
- Von Willebrand‘s disease
- Platelet deficiency (thrombocytopenia)

**FUNCTIONAL CAUSES**

Due to disturbed hypothalamo- pituitary- ovarian- endometrial axis

**COMMON CAUSES OF MENORRHAGIA**

- Dysfunctional uterine bleeding
- Fibroid uterus
- Adenomyosis
- Chronic tubo-ovarian mass

**PATHO –PHYSIOLOGY**

The current concept concludes that the abnormal bleeding is most likely due to local causes in the endometrium. There is some disturbance of the endometrial blood vessels and capillaries and coagulation of blood in and around blood vessels. These are probably related to alteration in the ratio of endometrial prostaglandins which are delicately balanced in haemostasis of menstruation.

The endometrial abnormalities may be primary or secondary to inco-ordination in the hypothalamo-pituitary-ovarian axis. It is thus more prevalent in extremes of reproductive period – adolescence and premenopause or following childbirth and abortion.

Emotional influences, worries, anxieties or sexual problems sometimes are enough to disturb the normal hormonal balance [(53)].

**SYMPTOMS OF MENORRHAGIA**

- Saturating multiple sanitary pads or tampons per hour
- Requiring two sanitary pads to contain uterine bleeding
- Waking up at night to change sanitary pads or tampons
- Prolonged bleeding that lasts beyond a week
- Passing large blood clots
- Inability to engage in routine daily activities
- Fatigue and weakness (signs of anaemia)
- Tiredness
- Shortness of breath
- Headache
- Lower abdominal pain

**INVESTIGATIONS**

- **Blood tests**

  A sample of blood may be evaluated for iron deficiency (anaemia) and other conditions, such as thyroid disorders or blood-clotting abnormalities.

- **Pap test**

  In this test, cells from the cervix are collected and tested for infection, inflammation or changes that may be cancerous or may lead to cancer.

- **Endometrial biopsy**

  Take a sample of tissue from the inside of the uterus to be examined by a pathologist.

- **Ultrasound scan**

  This imaging method uses sound waves to produce images of the uterus, ovaries and pelvis.

Based on the results of the initial tests, doctor may recommend further testings, including:

- **Sonohysterography**

  During this test, a fluid is injected through a tube into the uterus by way of vagina and cervix and then uses ultrasound to look for problems in the lining of the uterus.

- **Hysteroscopy**

  This exam involves inserting a tiny camera through the vagina and cervix into the uterus, which allow to seeing inside of the uterus.

**MANAGEMENT**

- General measures to improve the health status of the patient. Advice regarding proper diet, adequate rest during menses, oral administration of haematinics, vitamins and protein supplements and to maintain a menstrual calendar noting duration and extent of blood loss.
- Treat the cause.

In women suffering from DUB, consider:

- Oral non-steroidal anti-inflammatory drugs like mefenamic acid 500 mg t.d.s along with antacids. Other drugs in the category include naproxen, ponstan and ibuprofen
- Cyclic oral contraceptive pills.
- Oral progesterone - When taken for 10 or more days of each menstrual cycle, the hormone progesterone can help correct hormone imbalance and reduce menorrhagia.
- The hormonal IUD (Mirena) - This intrauterine device releases a type of progestin called levonorgestrel, which makes the uterine lining thin and decreases menstrual blood flow and cramping.
- Hysterectomy in selected cases.

**THERAPEUTIC MEASURES**

This includes

- Removal of an offending intrauterine contraceptive device.
- Myomectomy or hysterectomy for uterine fibroids.
- Wedge resection or hysterectomy for adenomyosis of the uterus.
- Laparoscopic lysis of adhesions for chronic PID.
- Electrocautery or laser vaporization of endometriosis and drainage of chocolate cysts in pelvic endometriosis.

- ❖ Hysterectomy with or without removal of the adnexa as per the age and the individual needs of the patient.
- ❖ In patients suffering from bleeding disorders, a haematologist‘s opinion should be sought [(54)].

**Dilation and curettage (D&C)**

In this procedure, opens (dilates) cervix and then scrapes or suctions tissue from the lining of uterus to reduce menstrual bleeding. Although this procedure is common and often treats acute or active bleeding successfully, may need additional D&C procedures if menorrhagia recurs.

**Uterine artery embolization**

For women whose menorrhagia is caused by fibroids, the Goal of this procedure is to shrink any fibroids in the uterus by blocking the uterine arteries and cutting off their blood supply.

During uterine artery embolization, the surgeon passes a Catheter through the large artery in the thigh (femoral artery) and guides the uterine arteries, where the blood vessel is injected with microspheres made of plastic.

**Focused ultrasound ablation**

Similar to uterine artery embolization, focused ultrasound ablation treats bleeding caused by fibroids by shrinking the fibroids. This procedure uses ultrasound waves to destroy the fibroid tissue. There are no incisions required for this procedure.

**Myomectomy**

This procedure involves surgical removal of uterine fibroids depending on the size, number and location of the fibroids.

**Endometrial ablation**

Using a variety of techniques permanently destroys the lining of the uterus (endometrium). After endometrial ablation, most women have much lighter periods.

**Endometrial resection**

This surgical procedure uses an electrosurgical wire loop to remove the lining of the uterus. Both endometrial ablation and endometrial resection benefit women who have very heavy menstrual bleeding.

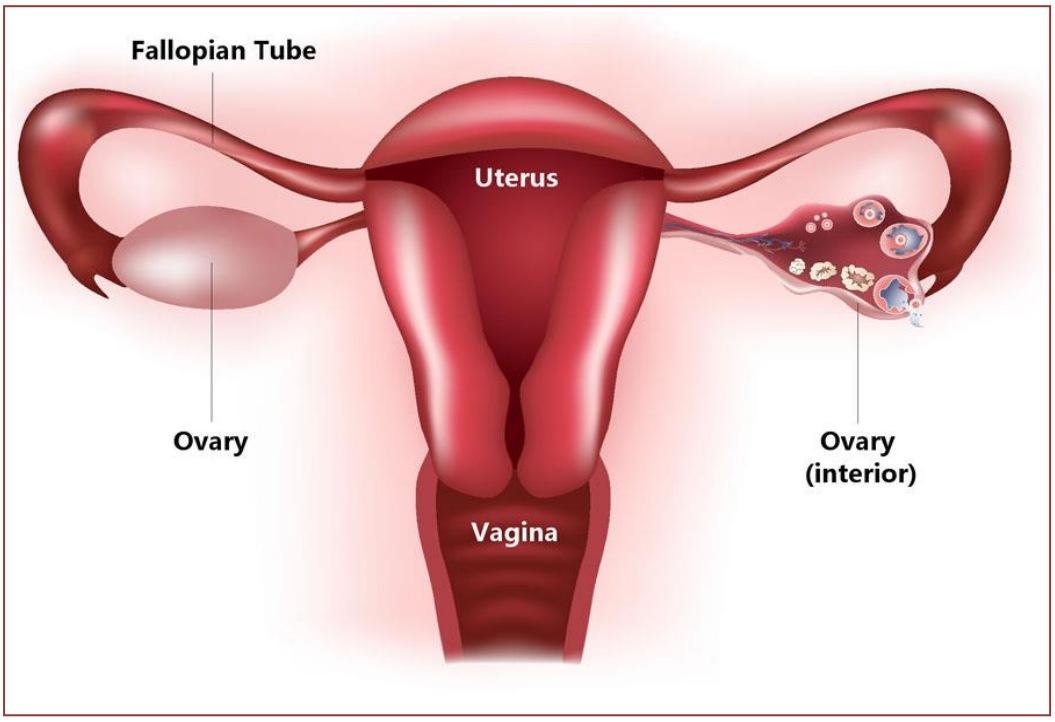
**Hysterectomy**

Hysterectomy is a surgical operation to remove the uterus and cervix. It is a permanent procedure that causes sterility and ends menstrual periods

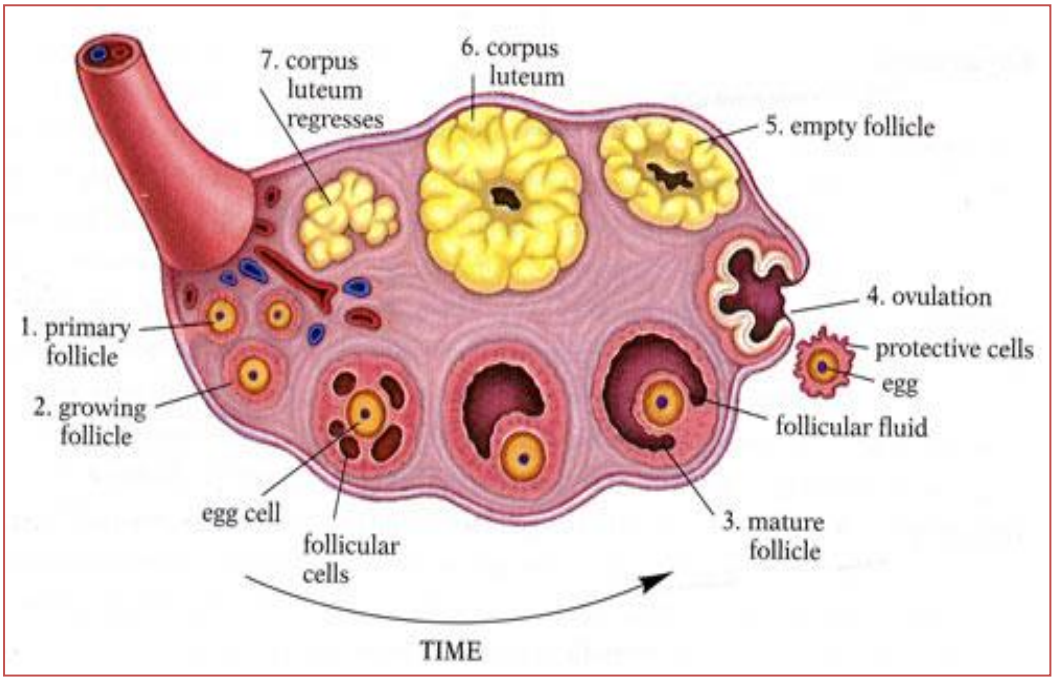
**COMPLICATIONS**

- Iron deficiency anaemia
- Tiredness
- Psychological disturbances
- Poor concentration [55].

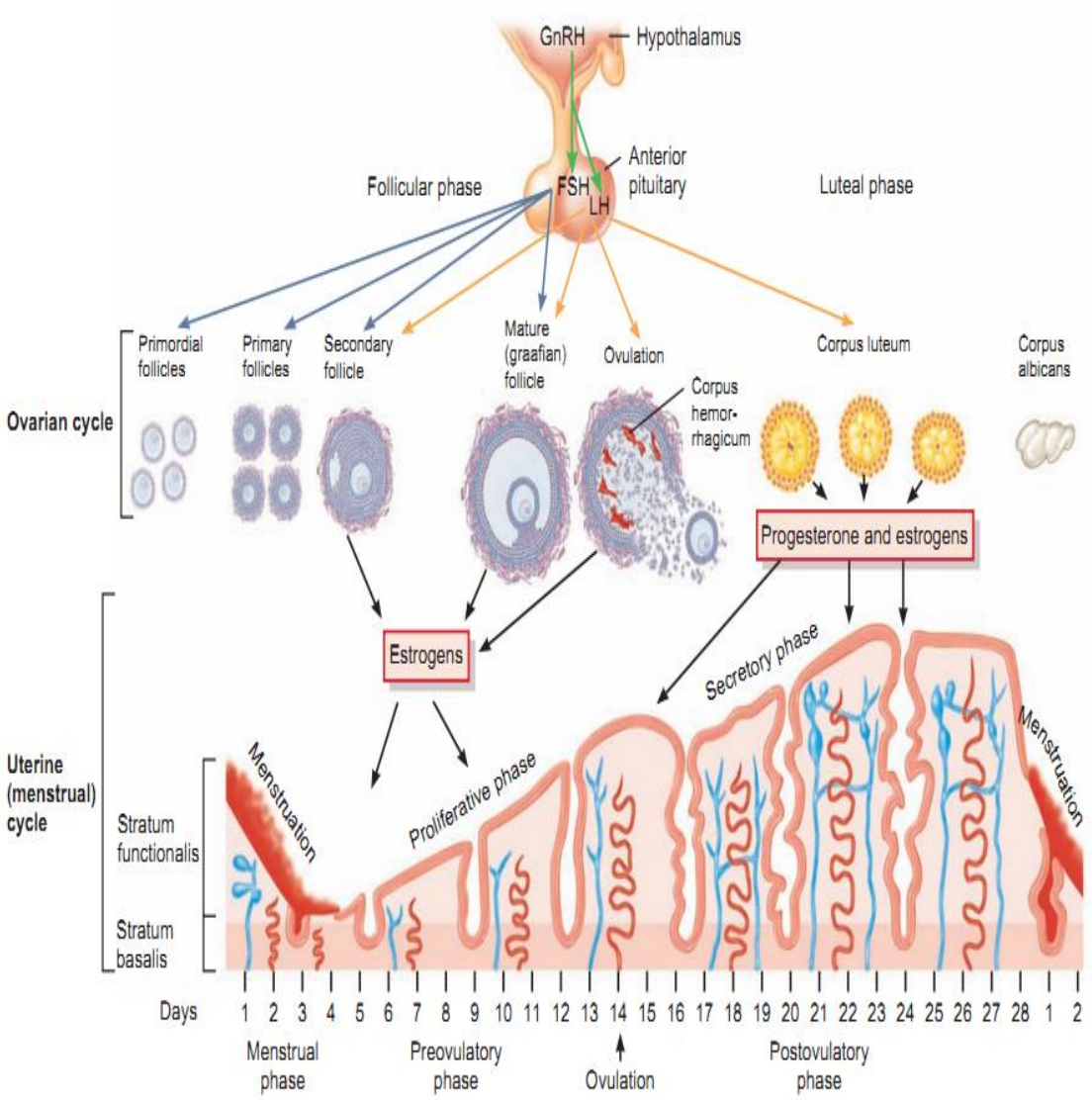
## CROSS SECTION OF INTERNAL GENITAL ORGANS



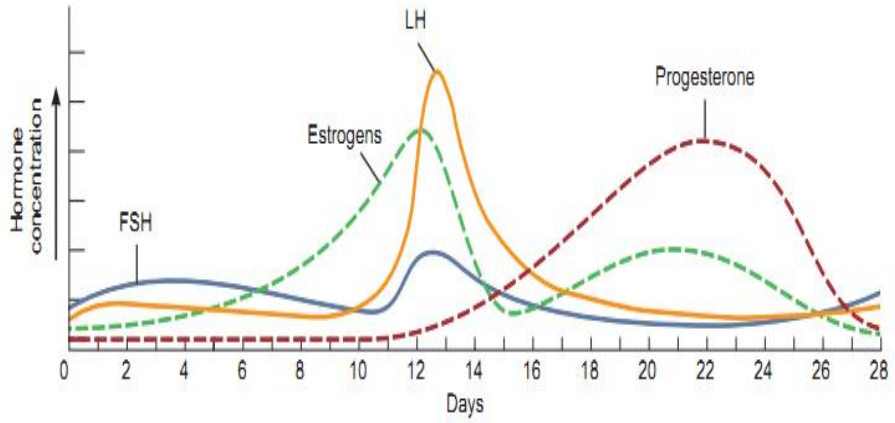

## CROSS SECTION OF OVARY SHOWING ITS LIFE CYCLE



## MENSTRUAL CYCLE




(a) Hormonal regulation of changes in the ovary and uterus




(b) Changes in concentration of anterior pituitary and ovarian hormones

# TRIAL MEDICINE

# TRIAL MEDICINE

## MAAMPISIN CHOORANAM

### INGREDIENTS:

| | |
|---|---|
| Nattu Maampisin (*Mangifera indica*) | : 35 gm |
| Nelli vattral ( *Phyllanthus emblica*) | : 35 gm |
| Panangkarkandu ( *Borassus flabellifer* ) | : 35 gm |

### STANDARD OPERATING PROCEDURE

### SOURCE OF RAW DRUGS:

The required raw drugs were obtained from a well reputed indigenous raw drug shop. The raw drugs taken for the study were authenticated by the Central Council of Research Institute of Siddha, Chennai, 600106.

### PURIFICATION OF RAW DRUGS:

Raw drugs were purified as mentioned in Sikitcha Ratna Deepam Sarakku Suthi Muraigal.

### PREPARATION:

The above given drugs were purified and grinded, then sieved it by using cloth and preserved it in air tight container as mentioned in the literature.

### DRUG STORAGE:

The trial drug was stored in clean dry air tight container and it was dispensed to the patients in pockets.

**DOSE** **:** 2 gm , tds (After food)

**ADJUVENT** **:** Ghee

**DURATION** **:** 1 to 15 days of menstruation for 3 consecutive cycles.

**REFERENCE** **:** Siddha Vaidhiya Pathartha Guna Vilakkam-Moola Varkkam Page No 596[(56)].

## LITERATURE REVIEW OF TRIAL DRUGS:

### 1. Maampisin :

Botanical Name : *Mangifera indica*

Family : Anacardiaceae

Suvai : Thuvarppu

Thanmai : Thatpam

Pirivu : Kaarppu[57]

Action : Astringent, Sedative[58]

Chemical Components: Tannins

Polyphenolics

Flavonoids

Triterpenoids

Mangiferin[59]

பொதுகுணம்:

பெரும்பாடெங் கேரத்தப் பேதியெங் கேமுக்கல்
தரும்பாழும் வெள்ளையெங்கே சாற்றாய் – கரும்பாம்பின்
நாதநிரி யாசஞ்செய் நங்காய் ! வனத்திலுறை
சூதநிரி யாசமெனச் சொல்[60].

**2. Nellivattral :**

Botanical Name : *Phyllanthus emblica*

Family : Phyllanthacee

Suvai : Pulippu, Thuvarppu, Inippu,

Veeryam : Thatpam

Pirivu : Inippu

Action : Astringent,

Chemical Components: Tannins

Flavonoids

Alkaloids

Phenolic compounds

Amino acids

Carbohydrates

Chebulinic acid[61]

பொதுகுணம்:

ஆகவன லஞ்சசிஅ சிர்க்கென்பு ருக்கிகண்ணோய்
தாக முதிரவித்தந் தாதுநஷ்டம் - மேகனத்தின்
இல்லிமுள்ளி போலருகல் எண்லகா மியவியங்கம்
நெல்லிமுள்ளி யாற்போ நினை[62]

### 3. Panangarkandu:

Botanical Name : *Borassus flabellifer*

Family : Arecaceae

Suvai : Inippu

Thanmai : Thatpam

Pirivu : Inippu

Action : Refrigerant [63]

Chemical Components: Phenolic compounds, Potassium, Iron, Phosphorus [64]

## MAAMPISIN CHOORANAM

# MATERIALS AND METHODS

# MATERIALS AND METHODS

**STUDY DESIGN:**

The clinical trial on Pitha Perumbadu (Menorrhagia) was decided to conduct as an open label study.

The study was approved by Institutional Ethics Committee (IEC) and the approved number is GSMC –CH – ME -5/003/2016. The study was registered in Clinical Trials Registry – India (CTRI) and the reference Number is CTRI/2018/03/012381.

**STUDY CENTRE:**

The entire study was conducted on patients at Out Patients Department of Government Siddha Medical College, Chennai in the premises of Arignar Anna Government Hospital for Indian Medicine and Homeopathy, Arumbakkam, Chennai – 106, during the period of 2016-2018.

**POPULATION:**

The population consists of all patients were attending the OPD of Arignar Anna Hospital, Arumbakkam, Chennai – 106. Sample consists of Pitha Perumbadu who satisfying the inclusion and exclusion criteria mentioned below:

**SAMPLE SIZE:**

30 patients

**STUDY DRUG:**

Maampisin Chooranam – 2 gm thrice a day with Ghee for Day 1 of menstruation to 15 days for 3 consecutive cycles.

**SELECTION CRITERIA:**

The population of pitha perumbadu rogam patients with the following signs and symptoms are taken into the clinical trial.

- Age 15 – 50 years
- Excessive menstruation
- Prolonged menstruation
- Presence of blood clots in menstrual bleeding

- Lower abdominal pain
- Low back ache
- Giddiness during menstruation
- Headache during menstruation
- Tiredness during menstruation
- USG report with fibroid uterus or PCOD.

**EXCLUSION CRITERIA:**

- Chocolate Cysts
- Adenomyosis
- Bleeding Disorders
- Hypothyroidism
- Ovarian Feminizing Tumors
- Abortion and Pregnancy
- Uterine Cancer
- Patient having IUCD
- Thrombocytopenic purpura
- Coagulopathy
- Severe anaemia (<6 gm)
- Vulnerable populations such as

  HIV positive

  TB affected individuals

**WITHDRAWAL CRITERIA:**

- Intolerance to the drug and development of any serious adverse effect during trial (if ADR is reported, it should be informed to SCRI) and the patient is directed to nearest Govt. Hospital.
- Patient turned unwilling to continue in the course of clinical trial.
- Poor compliance
- Any other acute illness which needs a rescue medication.

**EVALUATION OF CLINICAL PARAMETERS:**

Patients are clinically evaluated by the following parameters.

**A. HISTORY TAKING:**

Age, Occupation, Socio economic status, Complaints and its duration, previous illness, Family history, Personal habits, menstrual history were recorded in the case sheet for every patient at the time of first visit to the OP.

**B. INVESTIGATIONS:**

All the patients were subjected to the laboratory investigations before and after treatment.

- BLOOD:

  TC, DC, ESR, Hb, Blood Sugar ( R ), Serum cholesterol, Blood Urea, Serum Creatinine, Bleeding time and Clotting time.

- URINE:

  Albumin, Sugar, Deposits.

- USG FOR WHOLE ABDOMEN & PELVIS.

**ASSESSMENT OF MENSTRUAL BLOOD LOSS:**

Reduction of blood flow was assessed by

- Number of sanitary pad used before and after treatment
- Based on Pictorial Blood loss Assessment Chart (PBAC) before and after treatment.

**SIDDHA ASSESSMENTS:**

- Envagai thervugal
- Neerkuri
- Neikkuri

A case sheet format was prepared on the basis of the Siddha methodology ex: Envagai thervvugal, Mukkutram, Nilam, Kaalam, Udal thathukkal, Neerkuri and Neikuri. Individual case sheet was maintained for each patient at outpatient department.

# RESULTS AND OBSERVATION

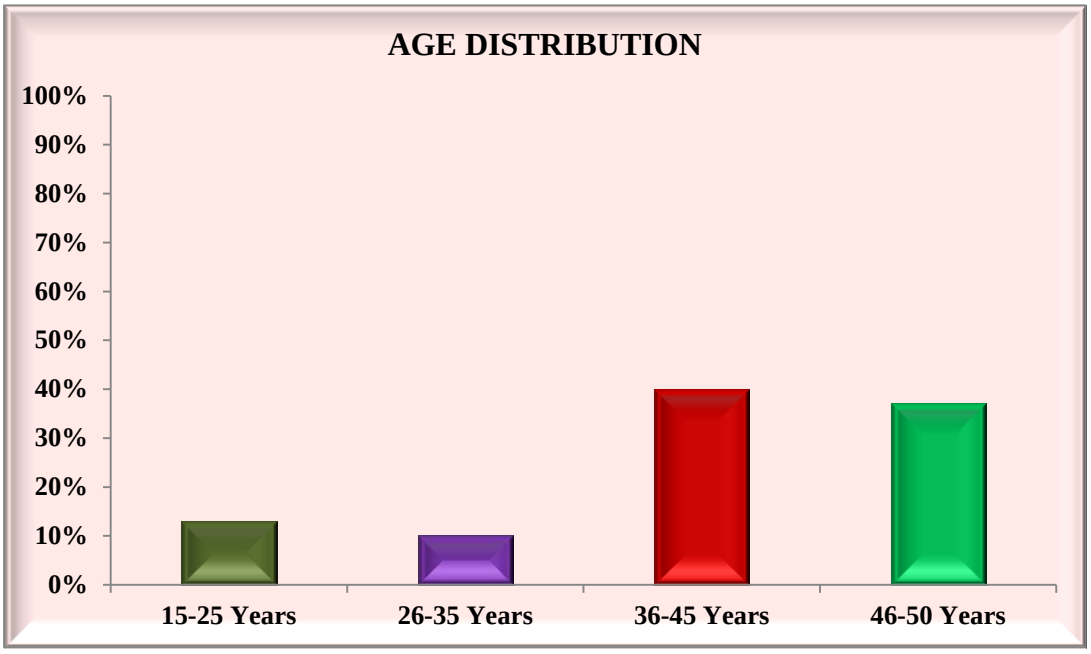
# RESULTS AND OBSERVATION

Pitha Perumbadu Rogam was carried out and analysed in 30 patients in the OPD Post Graduate Pothu Maruthuvam Department, Government Siddha Medical College, Chennai-106 attached to Arignar Anna Government Hospital of Indian Medicine during 2016 - 2018. The observations were made and tabulated with following criteria:

- Distribution of Age
- Occupational Distribution
- Distribution of Marital status
- Distribution of Socio-economic status
- Distribution of Food habits
- Distribution of Paruvakkalam
- Distribution of Thinai
- Distribution of Mukkutram
    - Vathakutram
    - Pittha kutram
    - Kabha kutram
- Distribution of Udal Thaathukal
- Distribution of Envagai thervugal
- Signs and Symptoms before and after treatment
- Number of pads used before and after treatment
- Hemoglobin level before and after treatment
- Bleeding time and Clotting time before and after treatment
- Gradating of results.

## 1. AGE DISTRIBUTION

| S.NO | AGE | NO. OF CASES | PERCENTAGE (%) |
|---|---|---|---|
| 1 | 15-25 YEARS | 4 | 13% |
| 2 | 26-35 YEARS | 3 | 10% |
| 3 | 36-45 YEARS | 12 | 40% |
| 4 | 46-50 YEARS | 11 | 37% |

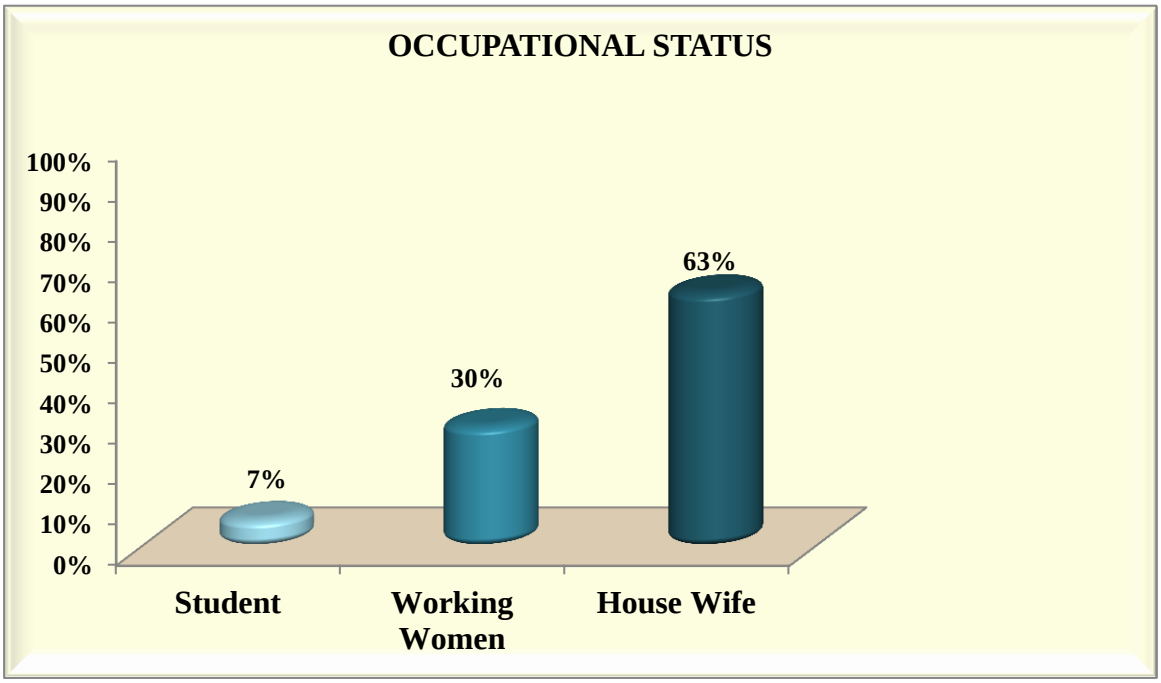



**INFERENCE:**

According to the above mentioned data, 40% of Patients in the age group of 36-45 years were mostly affected, 37% of patients were in the age group of 46-50 years. 13% of patients were in the age group of 15-25, 10% of patients were in the age group of 26-35 Years.

## 2. OCCUPATIONAL STATUS

| S.NO | NATURE OF WORK | NO.OF CASES | PERCENTAGE (%) |
|---|---|---|---|
| 1. | STUDENT | 2 | 7% |
| 2. | WORKING WOMEN | 9 | 30% |
| 3. | HOUSE WIFE | 19 | 63% |

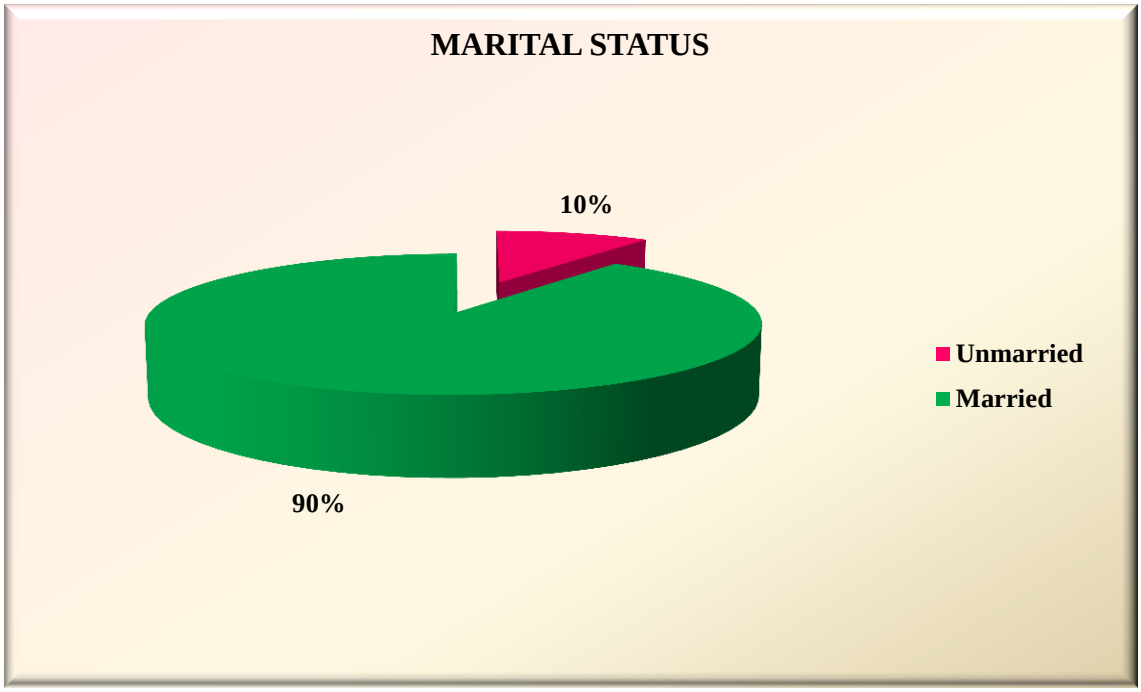



## INFERENCE

Among 30 patients, 19 patients (63%) were house wifes, 9 patients (30%) were working women and 2 patients (7%) were students.

### 3. MARITAL STATUS

| S.NO | STATUS | NO OF CASES | PERCENTAGE |
|---|---|---|---|
| 1 | UNMARRIED | 3 | 10% |
| 2 | MARRIED | 27 | 90% |

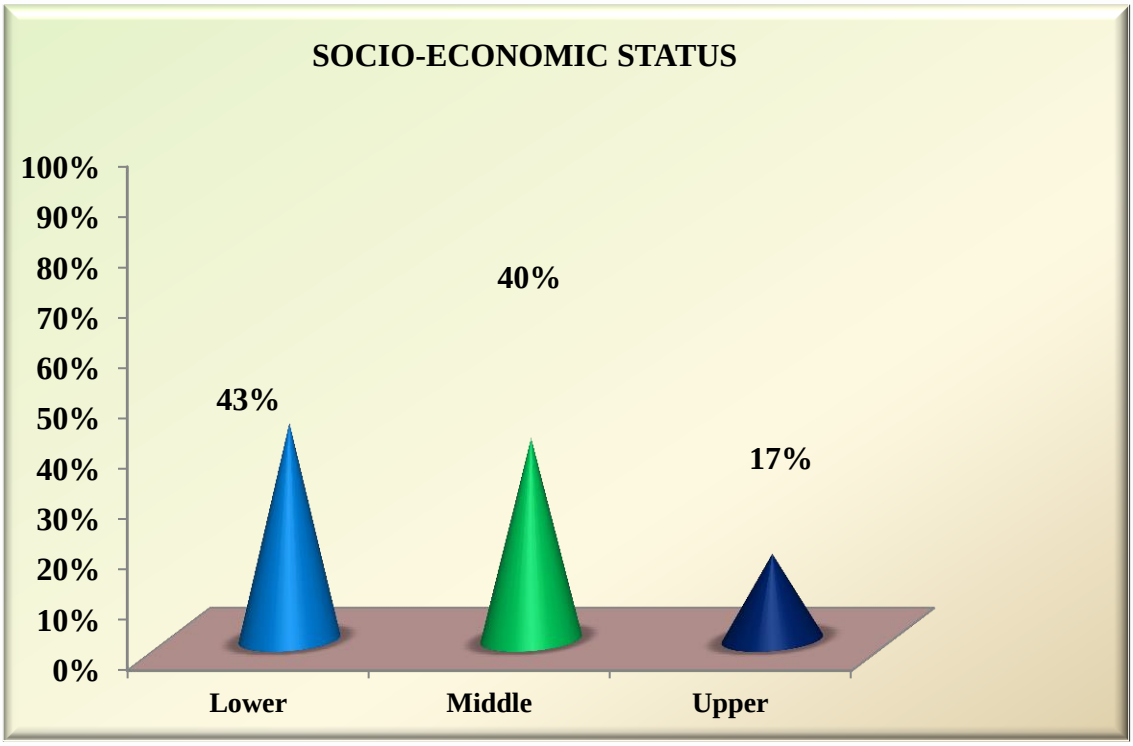



### INFERENCE

Among 30 cases, 27 patients (90%) were married and 3 patients (10%) were unmarried.

## 4. SOCIO-ECONOMIC STATUS

| S.NO | STATUS<br><br>INCOME PER ANNUM | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | LOWER<br>(BELOW 2 LAKHS) | 13 | 43% |
| 2. | MIDDLE<br>(UPTO 2 LAKHS) | 12 | 40% |
| 3. | UPPER<br>(ABOVE 5 LAKHS) | 5 | 17% |

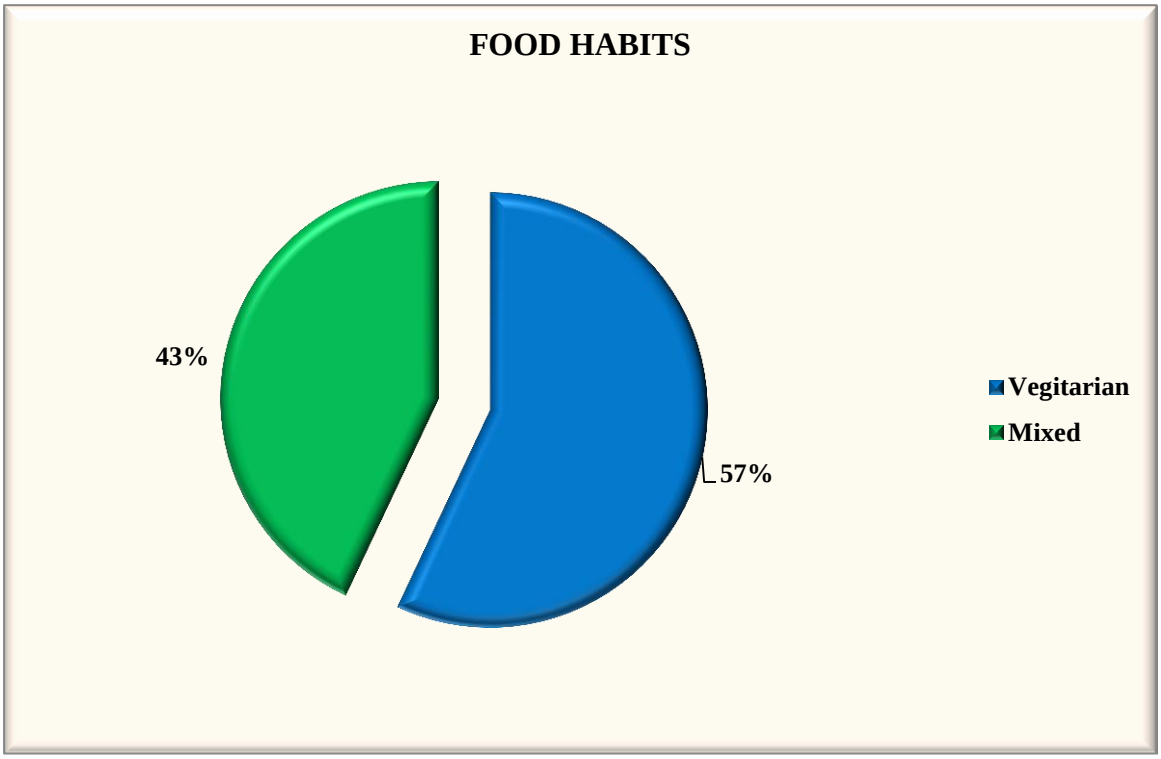



## INFERENCE

Out of 30 patients, 13 patients (43%) were from lower income group, 12 patients (40%) were from middle income group and 5 patients (17%) were from upper income group.

## 5. FOOD HABITS

| S.NO | FOOD HABITS | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | VEGETARIAN | 17 | 57% |
| 2. | MIXED DIET | 13 | 43% |

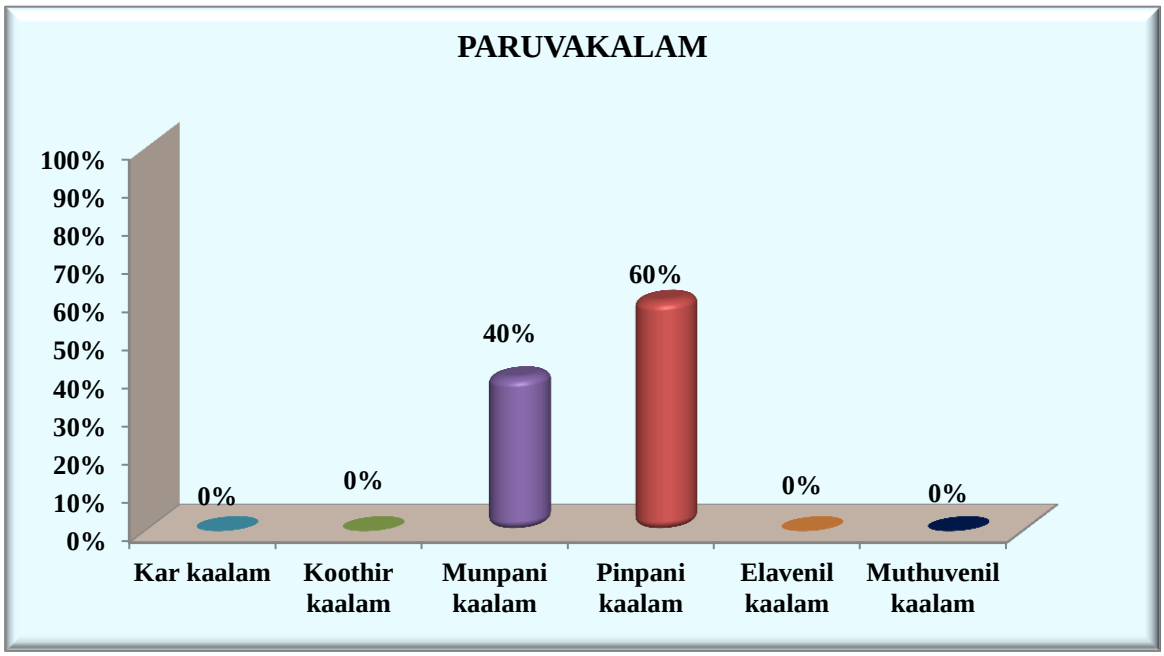



**INFERENCE**

Among 30 patients, 13 patients (43%) were taking mixed diet and 17 patients (57%) were taking vegetarian diet.

## 6. PARUVAKALAM

| S.NO | KAALAM | NO. OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | KAAR KAALAM (AUG16-OCT15) | 0 | 0% |
| 2. | KOOTHIR KAALAM (OCT16-DEC15) | 0 | 0% |
| 3. | MUNPANI KAALAM (DEC16-FEB15) | 12 | 40% |
| 4. | PINPANI KAALAM (FEB16-APR15) | 18 | 60% |
| 5. | ELAVENIL KAALAM (APR16-JUN15) | 0 | 0% |
| 6. | MUTHUVENIL KAALAM (JUN16-AUG15) | 0 | 0% |

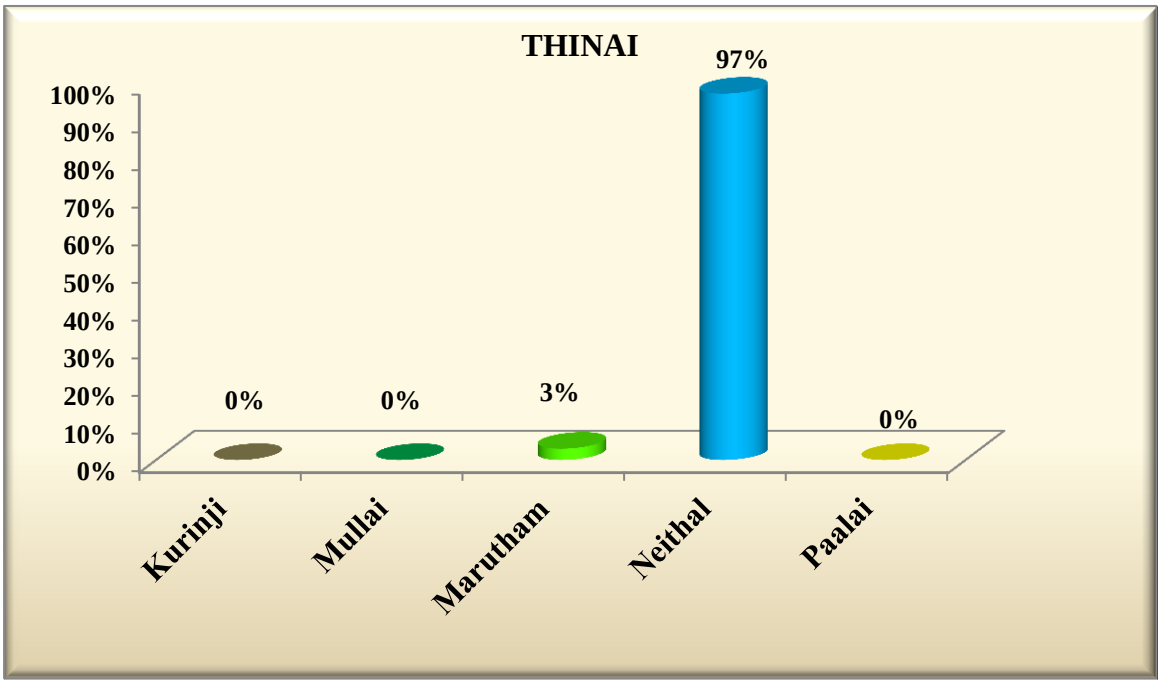



**INFERENCE:**

Among 30 patients, 18 patients (60%) were reported in Pinpani Kaalam, 12 patients (40%) were reported in Munpani Kaalam.

**7. THINAI**

| S.NO | THINAI | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | KURINJI | 0 | 0% |
| 2. | MULLAI | 0 | 0% |
| 3. | MARUTHAM | 1 | 3% |
| 4. | NEITHAL | 29 | 97% |
| 5. | PAALAI | 0 | 0% |



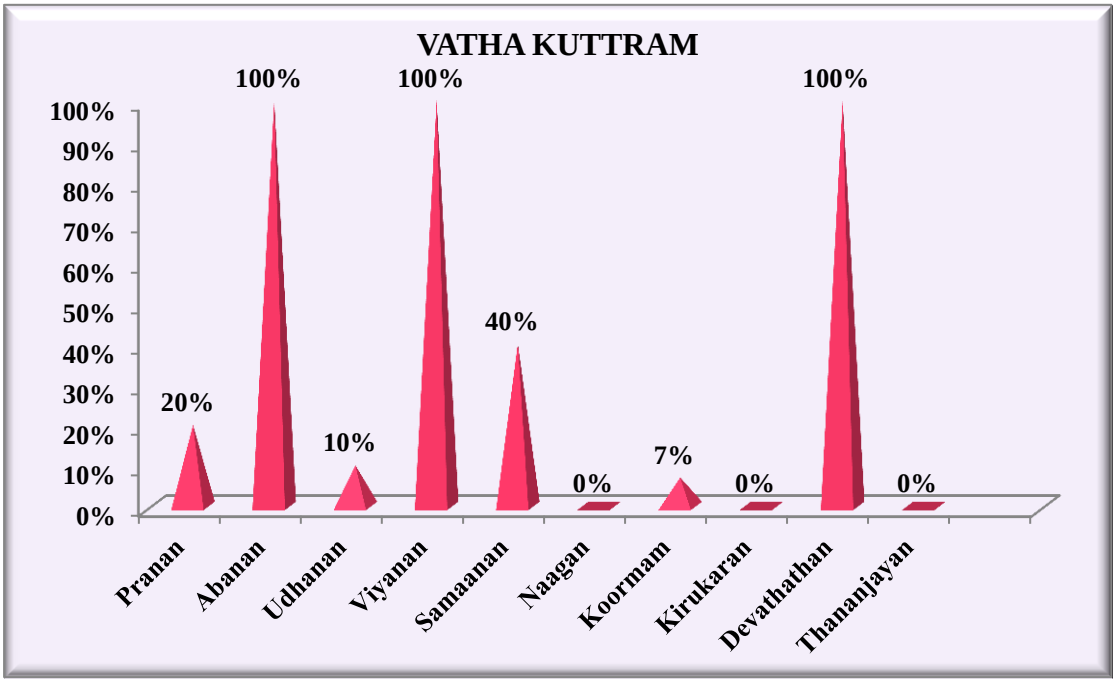

**INFERENCE**

Among 30 patients, 29 patients (97%) were from Neithal thinai and 1 patient (3%) was from Marutham thinai.

## 8. MUKKUTRAM

### a. VATHA KUTTRAM

| S.NO | TYPES OF VATHAM | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | PRANAN | 6 | 20% |
| 2. | ABANAN | 30 | 100% |
| 3. | UDHANAN | 3 | 10% |
| 4. | VIYANAN | 30 | 100% |
| 5. | SAMAANAN | 12 | 40% |
| 6. | NAAGAN | 0 | 0% |
| 7. | KOORMAN | 2 | 7% |
| 8. | KIRUGARAN | 0 | 0% |
| 9. | DEVATHATHAN | 30 | 100% |
| 10. | THANANJAYAN | 0 | 0% |

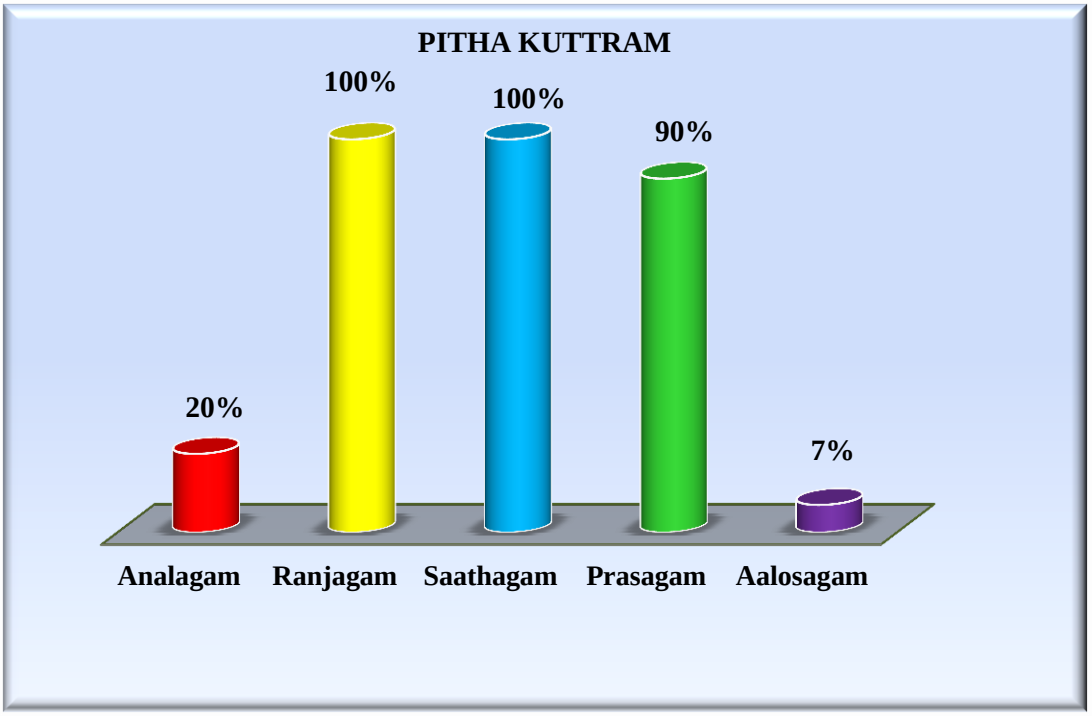



**INFERENCE**

Out of 30 patients, Abanan,Viyanan and Devathathan were affected in all the 100% of patients, Koorman was affected in 7% of patients, Pranan was affected in 20% of patients and Samanan was affected in 40% of patients.

## a. PITHAKKUTRAM

| S.NO | TYPES OF PITHAM | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | ANALAGAM | 12 | 40% |
| 2. | RANJAGAM | 30 | 100% |
| 3. | SAATHAGAM | 30 | 100% |
| 4. | PRASAGAM | 27 | 90% |
| 5. | ALOSAGAM | 2 | 7% |

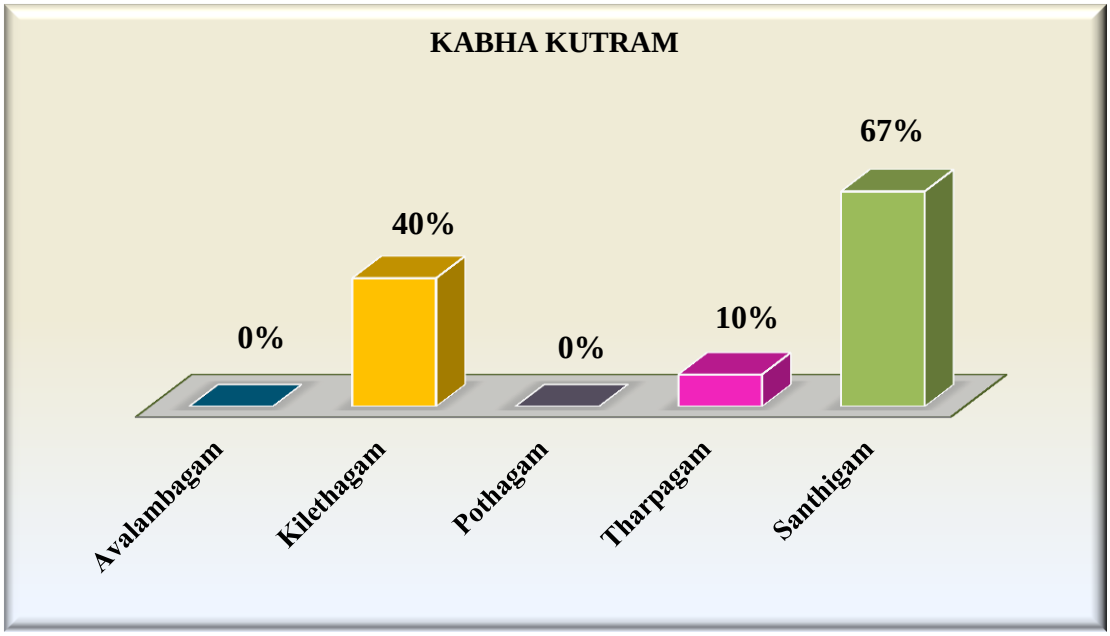



**INFERENCE**

Out of 30 patients, Saathagam and Ranjagam were affected in all the 100% of patients, Prasagam was affected in 90% of patients, Alosagam was affected in 7% of patients and Analagam was affected in 40% of patients.

## c. KABHAKUTTRAM

| S.NO | TYPES OF KABHAM | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | AVALAMBAGAM | 0 | 0% |
| 2. | KILETHAGAM | 12 | 40% |
| 3. | POTHAGAM | 0 | 0% |
| 4. | THARPAGAM | 3 | 10% |
| 5. | SANTHIGAM | 20 | 67% |

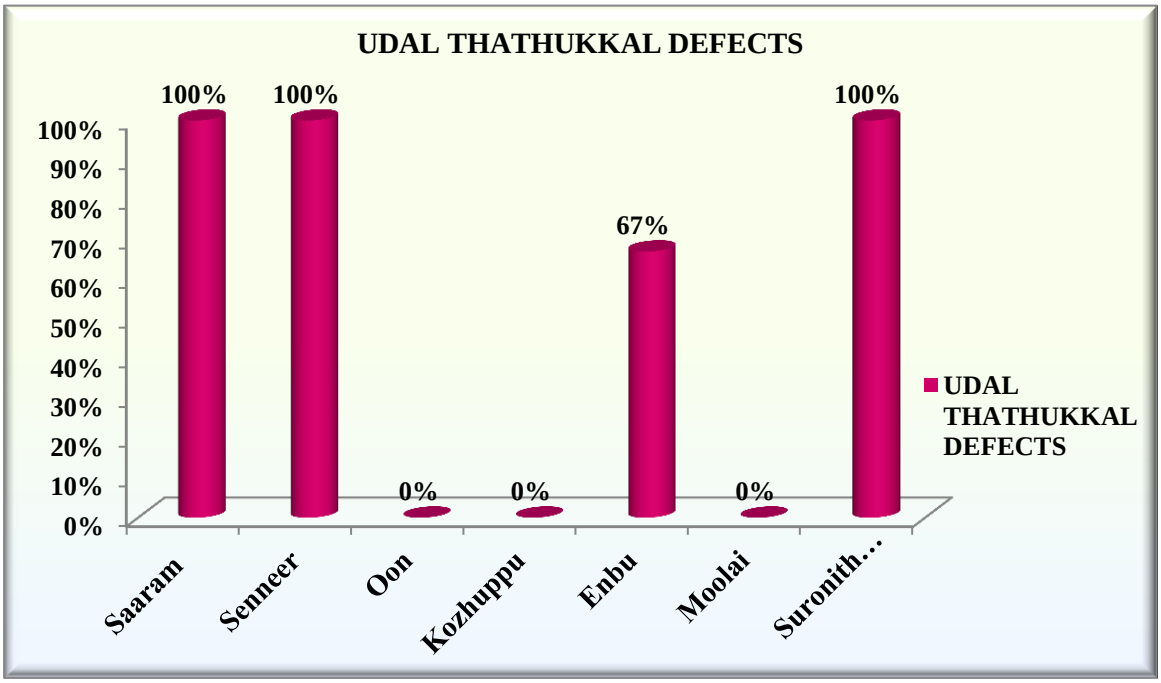



**INFERENCE**

Among 30 patients, Santhigam was affected in 67% of patients, Kilethagam was affected in 40% of patients and Tharpagam was affected in 10% of patients.

## 9. DEFECTS IN UDALTHATHUKKAL

| S.NO | UDAL THATHUKKAL | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | SAARAM | 30 | 100% |
| 2. | SENNEER | 30 | 100% |
| 3. | OON | 0 | 0% |
| 4. | KOZHUPPU | 0 | 0% |
| 5. | ENBU | 20 | 67% |
| 6. | MOOLAI | 0 | 0% |
| 7. | SURONITHAM | 30 | 100% |

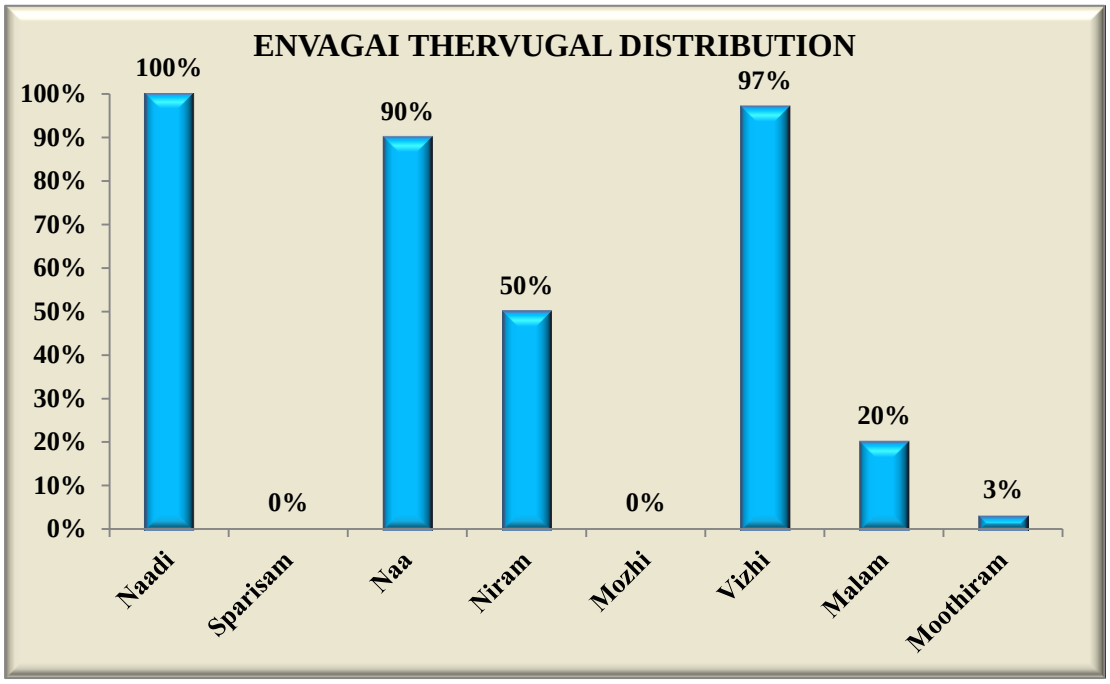



## INFERENCE

Out of 30 patients, Saaram and Suronitham were affected in all the 30 patients (100%), Senneer was affected in 25 patients (83%) and Enbu was affected in 20 patients (67%).

**10. EN VAGAI THERVUGAL**

| S.NO | ENVAGAI THERVUGAL | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | NAADI | 30 | 100% |
| 2. | SPARISAM | 0 | 0% |
| 3. | NAA | 27 | 90% |
| 4. | NIRAM | 15 | 50% |
| 5. | MOZHI | 0 | 0% |
| 6. | VIZHI | 29 | 97% |
| 7. | MALAM | 6 | 20% |
| 8 | MOOTHIRAM | 1 | 3% |

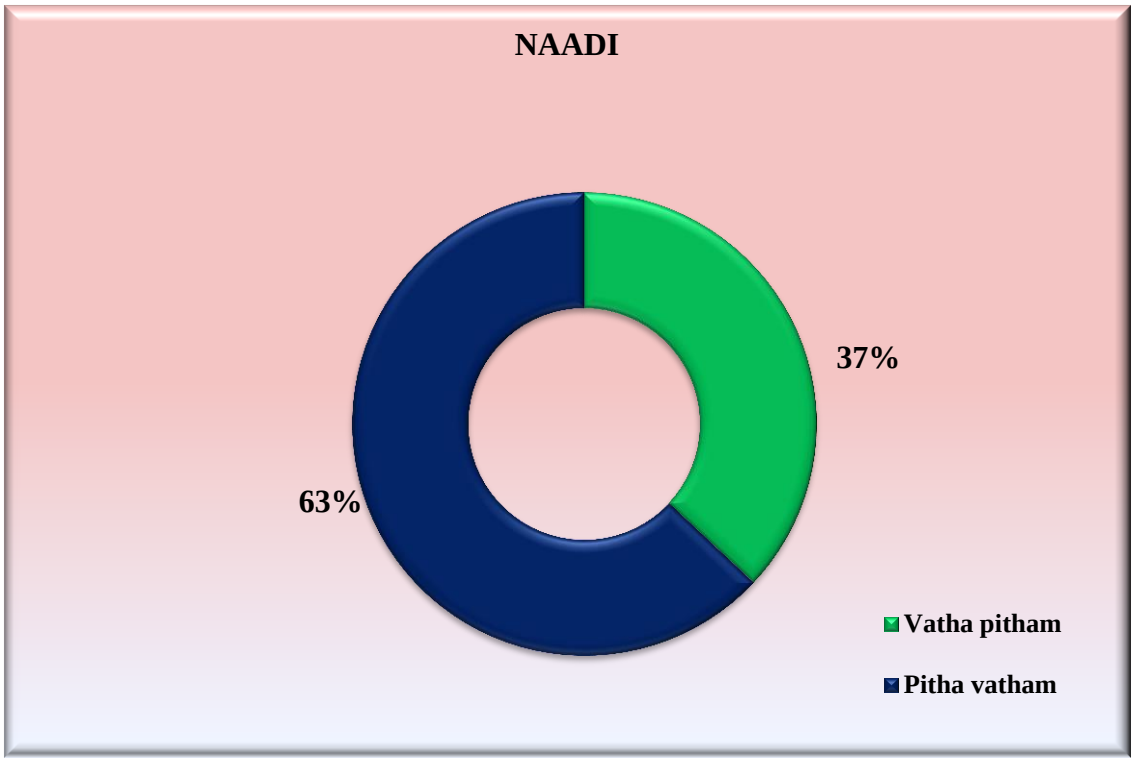



**INFERENCE**

Among 30 patients, Naadi was affected in all the 30 patients (100% ), Vizhi was affected in 29 patients (97%), Naa was affected in 27 patients (90%), Niram affected in 15 patients (50%), Malam was affected in 6 patients (20%) and Moothiram was affected in 1 patient (3%).

## NAADI

| S.NO | NAADI | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1 | PITHA VATHAM | 19 | 63% |
| 2 | VATHA PITHAM | 11 | 37% |

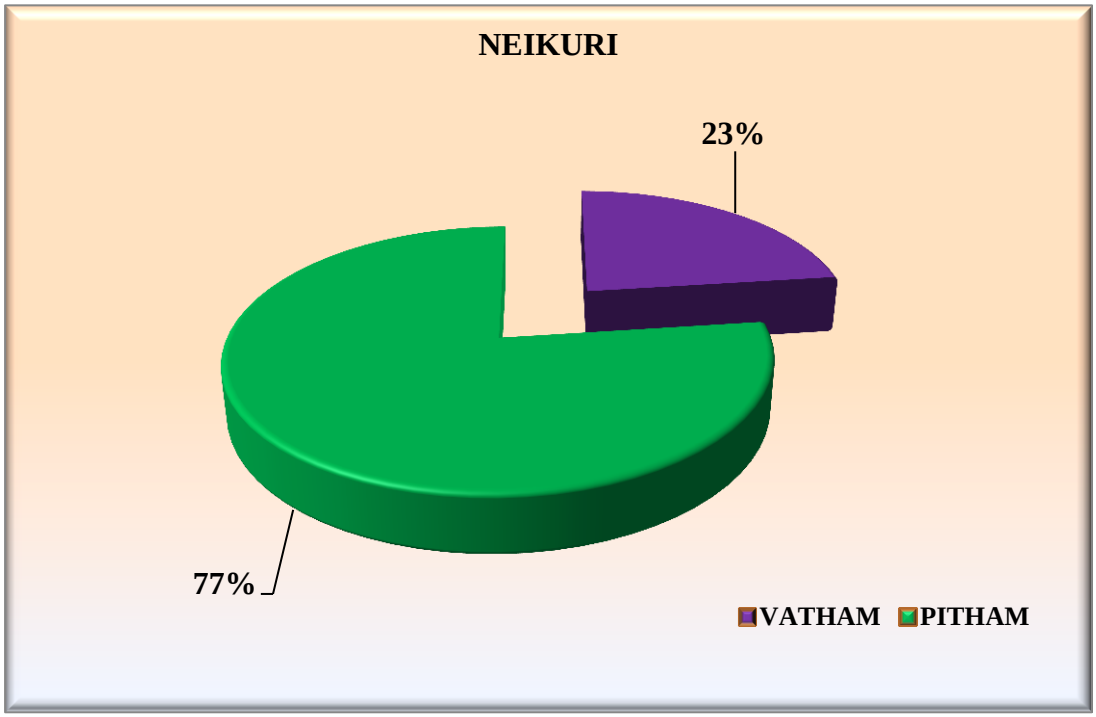



**INFERENCE**

Among 30 patients, 19 patients (63%) had Pitha Vatha naadi and 11 patients (37%) had Vadha Pitha naadi.

**NEIKURI**

| S.NO | THATHU | NEIKURI | NO.OF CASES | PERCENTAGE |
|---|---|---|---|---|
| 1. | Vatham | Spread Like Snake | 7 | 23% |
| 2. | Pitham | Spread Like Ring | 23 | 77% |
| 3 | Kabham | Spread like pearl | 0 | 0% |

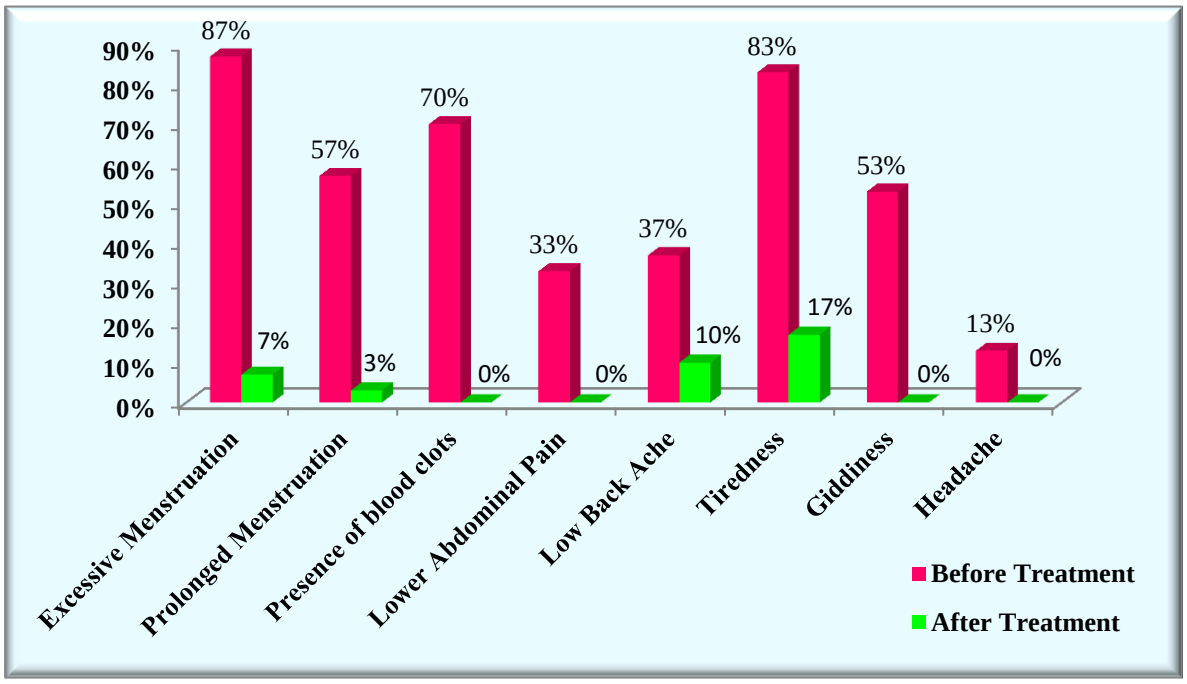



**INFERENCE**

Among the urine sample of 30 patients, 23 samples (77%) show Pitha neer and 7 samples (23%) show Vatha neer.

## 11. SIGNS AND SYMPTOMS

| S. NO | SIGNS AND SYMPTOMS | BEFORE TREATMENT | | AFTER TREATMENT | |
|---|---|---|---|---|---|
| | | NO.OF CASES | PERCE NTAGE | NO.OF CASES | PERCEN TAGE |
| 1. | Excessive Menstruation | 26 | 87% | 2 | 7% |
| 2. | Prolonged Menstruation | 17 | 57% | 1 | 3% |
| 3 | Presence Of Blood Clots | 21 | 70% | 0 | 0% |
| 3. | Lower Abdominal Pain | 10 | 33% | 0 | 0% |
| 4. | Low Back Ache | 11 | 37% | 3 | 10% |
| 5. | Tiredness | 27 | 83% | 5 | 17% |
| 6. | Giddiness | 16 | 53% | 0 | 0% |
| 7. | Head Ache | 4 | 13% | 0 | 0% |




## INFERENCE

Excessive menstrual bleeding after treatment were drawn from 87% to 7%, prolonged menstrual bleeding were drawn from 57% to 3%, presence of blood clots were drawn from 70% to 0%,lower abdominal pain were drawn from 33% to 0%,Low back ache were drawn from 37% to 10%, Tiredness were drawn from 83% to 17%, giddiness from 53% were drawn to 0%, Headache from 13% were drawn to 0%.

**12. NUMBER OF PADS**

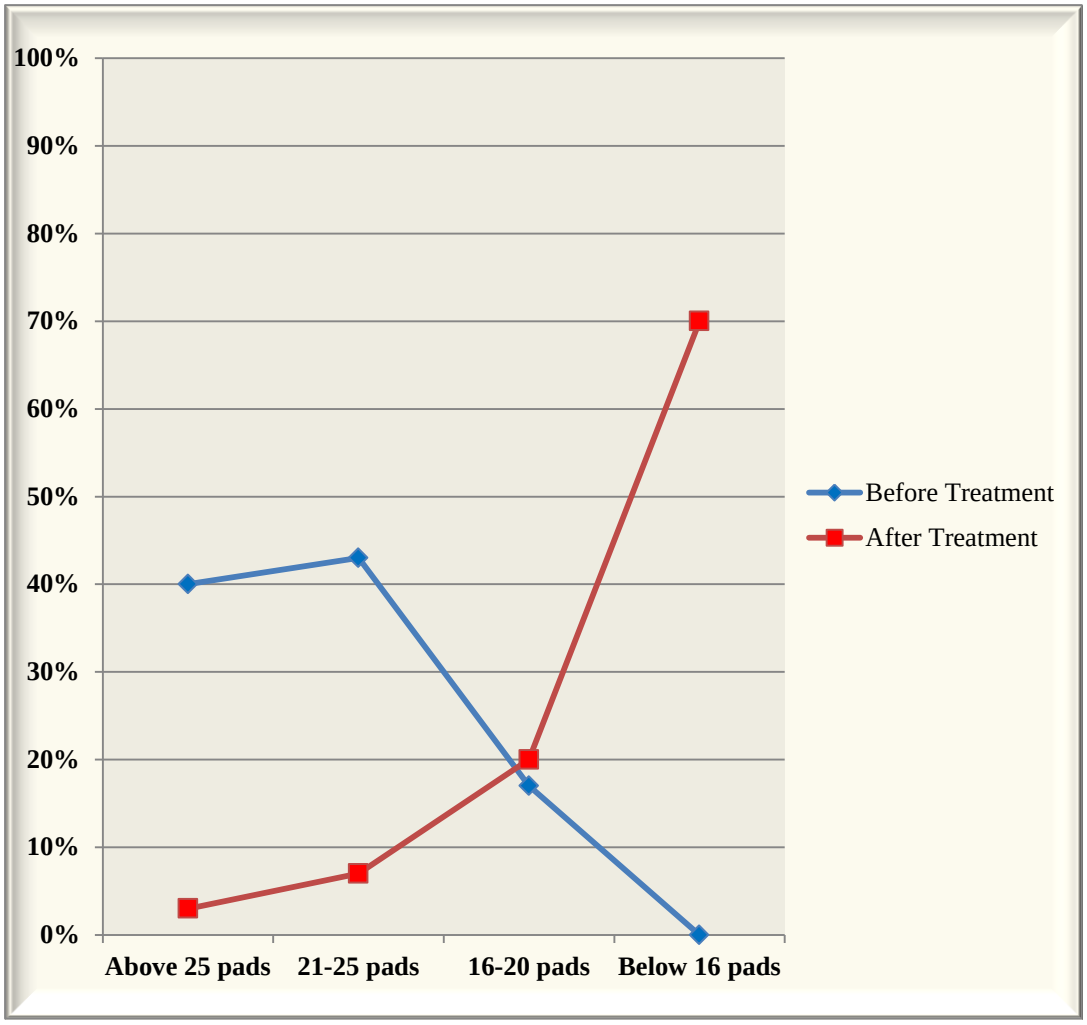
**BEFORE TREATMENT**

| S.NO | NO.OF PADS/ CYCLE | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1 | ABOVE 25 PADS | 12 | 40% |
| 2 | 21 - 25 PADS | 13 | 43% |
| 3 | 16 - 20 PADS | 5 | 17% |
| 4 | BELOW 16 PADS | 0 | 0% |

**AFTER TREATMENT**

| S.NO | NO.OF PADS/CYCLE | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1 | ABOVE 25 PADS | 1 | 3% |
| 2 | 21 - 25 PADS | 2 | 7% |
| 3 | 16 - 20 PADS | 6 | 20% |
| 4 | BELOW 16 PADS | 21 | 70% |

**NUMBER OF PADS BEFORE AND AFTER TREATMENT**




**INFERENCE**

After treatment, patients using above 25 pads were drawn from 40% to 3%, the patients using 21-25 pads were drawn from 43% to 7%, the patients using 16-20 pads were drawn from 17% to 20% and the patients using below 16 pads were increased from 0 to 70%.

## 13. CLINICAL PROGNOSIS

**MENSTURAL BLOOD LOSS ASSESSMENT SCORE**

| S.NO | OP.NO | BEFORE TREATMENT | AFTER TREATMENT | PROGNOSIS |
|---|---|---|---|---|
| 1 | 4819 | 335 | 95 | Good |
| 2 | 684 | 295 | 145 | Moderate |
| 3 | 8610 | 276 | 180 | Mild |
| 4 | 891 | 340 | 80 | Good |
| 5 | 124 | 350 | 100 | Good |
| 6 | 2768 | 323 | 95 | Good |
| 7 | 8802 | 355 | 185 | Mild |
| 8 | 5812 | 250 | 95 | Good |
| 9 | 3196 | 405 | 125 | Moderate |
| 10 | 1004 | 402 | 100 | Good |
| 11 | 3663 | 211 | 98 | Good |
| 12 | 3797 | 285 | 95 | Good |
| 13 | 8539 | 265 | 100 | Good |
| 14 | 3842 | 308 | 85 | Good |
| 15 | 825 | 295 | 135 | Moderate |
| 16 | 6713 | 213 | 90 | Good |
| 17 | 6942 | 305 | 100 | Good |
| 18 | 2756 | 284 | 100 | Good |
| 19 | 5585 | 295 | 90 | Good |
| 20 | 7293 | 272 | 100 | Good |
| 21 | 5007 | 225 | 130 | Moderate |
| 22 | 728 | 230 | 95 | Good |
| 23 | 4927 | 360 | 140 | Moderate |
| 24 | 6610 | 200 | 95 | Good |
| 25 | 8665 | 230 | 100 | Good |
| 26 | 8404 | 275 | 95 | Good |
| 27 | 5582 | 320 | 90 | Good |
| 28 | 320 | 420 | 300 | Mild |
| 29 | 7497 | 310 | 99 | Good |
| 30 | 1397 | 355 | 145 | Moderate |

**Note:** Improvement is assessed by based on the PBAC (Pictorial Blood loss Assessment Chart) score

≤ 100 : Good Improvement

101 – 150 : Moderate Improvement

> 150 : Mild Improvement

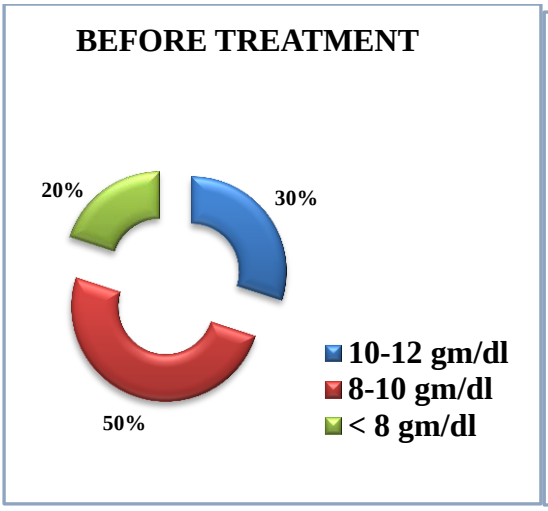
## 14.. HAEMATOLOGICAL OBSERVATION

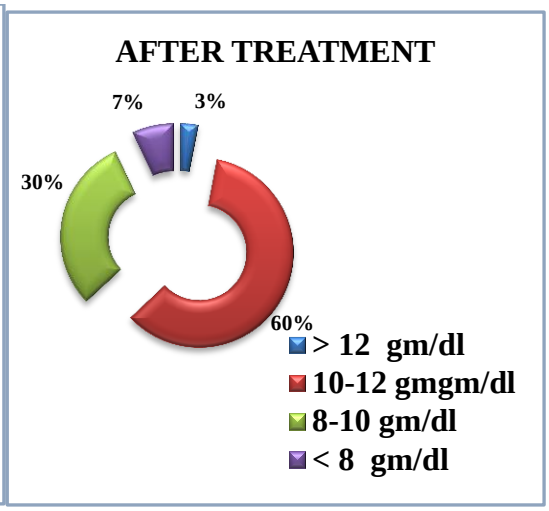
### BEFORE TREATMENT

| S.NO | HAEMOGLOBIN LEVEL | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1 | > 12 gm/ dl | 0 | 0% |
| 2 | 10 - 12 gm/dl | 9 | 30% |
| 3 | 8 - 10 gm/dl | 15 | 50% |
| 4 | < 8 gm/dl | 6 | 20% |

### AFTER TREATMENT

| S.NO | HAEMOGLOBIN LEVEL | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1 | > 12 gm/ dl | 1 | 3% |
| 2 | 10 - 12 gm/dl | 18 | 60% |
| 3 | 8 - 10 gm/dl | 9 | 30% |
| 4 | < 8 gm/dl | 2 | 7% |



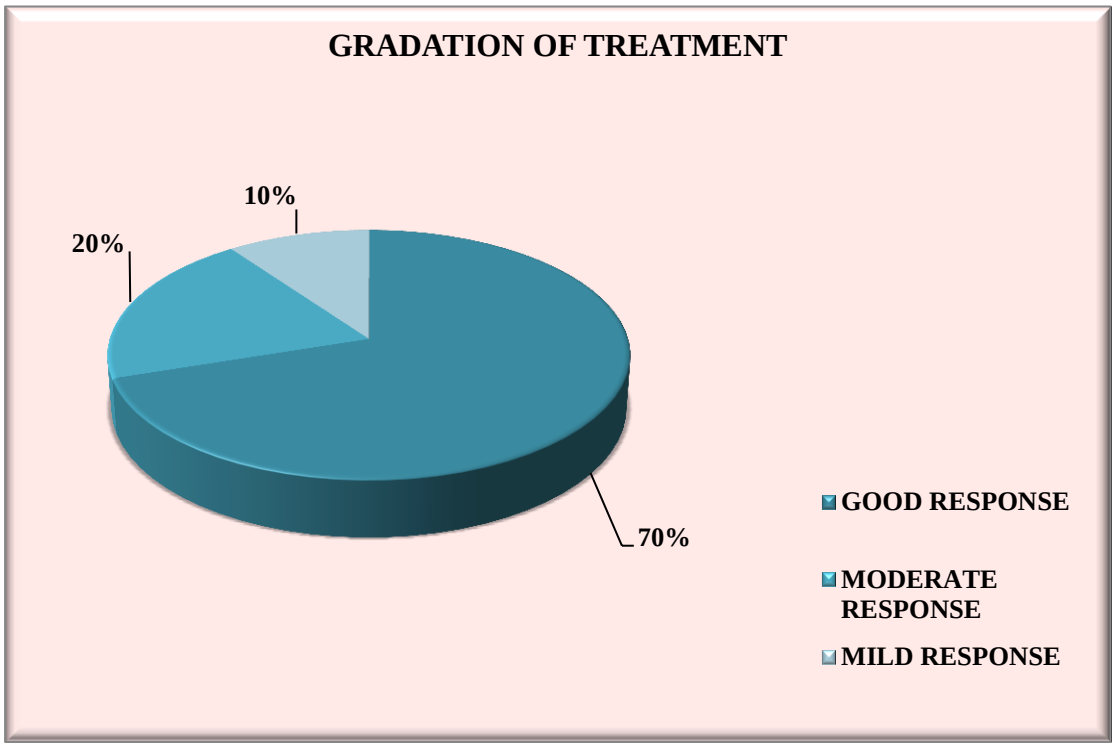




### INFERENCE

After treatment 12-15 gms of Hb were about 3%, 10-12 gms of Hb were about 63%, 8-10 gms of Hb were about 30% and 6-8 gms of Hb were about 7%.

## GRADATION OF RESULTS

| S.NO | GRADE OF RESULTS | NO.OF CASES | PERCENTAGE |
|---|---|---|---|
| 1. | GOOD RESPONSE | 21 | 70% |
| 2. | MODERATE RESPONSE | 6 | 20% |
| 3 | MILD RESPONSE | 3 | 10% |




**INFERENCE**

Good response of treatment was about 70%, moderate response of treatment was about 20% and mild response was in 10% of the patients.

## NUMBER OF PADS USED BY THE PATIENTS

## BEFORE AND AFTER TREATMENT

| S. NO | OP. NO | PATIENT'S AGE | NUMBER OF PADS FOR A CYCLE | |
|---|---|---|---|---|
| | | | BEFORE TREATMENT | AFTER TREATMENT |
| 1 | 4819 | 38 | 21 | 9 |
| 2 | 684 | 28 | 32 | 20 |
| 3 | 8610 | 48 | 26 | 21 |
| 4 | 891 | 37 | 22 | 8 |
| 5 | 124 | 23 | 30 | 10 |
| 6 | 2768 | 45 | 20 | 9 |
| 7 | 8802 | 17 | 39 | 21 |
| 8 | 5812 | 28 | 21 | 13 |
| 9 | 3196 | 22 | 28 | 16 |
| 10 | 1004 | 30 | 25 | 14 |
| 11 | 3663 | 44 | 16 | 8 |
| 12 | 3797 | 37 | 22 | 10 |
| 13 | 8539 | 42 | 23 | 10 |
| 14 | 3842 | 37 | 22 | 9 |
| 15 | 825 | 45 | 27 | 20 |
| 16 | 6713 | 23 | 17 | 10 |
| 17 | 6942 | 44 | 29 | 9 |
| 18 | 2756 | 46 | 25 | 14 |
| 19 | 5585 | 38 | 21 | 9 |
| 20 | 7293 | 35 | 19 | 11 |
| 21 | 5007 | 47 | 22 | 18 |
| 22 | 728 | 41 | 23 | 13 |
| 23 | 4927 | 33 | 26 | 16 |
| 24 | 6610 | 36 | 20 | 10 |
| 25 | 8665 | 37 | 25 | 14 |
| 26 | 8404 | 42 | 26 | 13 |
| 27 | 5582 | 42 | 21 | 11 |
| 28 | 320 | 41 | 30 | 26 |
| 29 | 7497 | 47 | 22 | 10 |
| 30 | 1397 | 42 | 26 | 17 |

## HAEMOGLOBIN LEVEL
## BEFORE AND AFTER TREATMENT

| S. NO | OP. NO | PATIENT'S AGE | HEMOGLOBIN LEVEL IN GMS/100ML OF BLOOD | |
|---|---|---|---|---|
| | | | BEFORE TREATMENT | AFTER TREATMENT |
| 1 | 4819 | 38 | 8.1 | 10.3 |
| 2 | 684 | 28 | 7.9 | 9.1 |
| 3 | 8610 | 48 | 9.0 | 10.4 |
| 4 | 891 | 37 | 11.5 | 12.0 |
| 5 | 124 | 23 | 6.3 | 7.7 |
| 6 | 2768 | 45 | 9.1 | 10.0 |
| 7 | 8802 | 17 | 9.8 | 11.0 |
| 8 | 5812 | 28 | 7.7 | 9.3 |
| 9 | 3196 | 22 | 8.5 | 10.1 |
| 10 | 1004 | 30 | 6.8 | 7.5 |
| 11 | 3663 | 44 | 8.3 | 9.0 |
| 12 | 3797 | 37 | 7.1 | 8.5 |
| 13 | 8539 | 42 | 10.2 | 11.1 |
| 14 | 3842 | 37 | 9.7 | 10.6 |
| 15 | 825 | 45 | 9.0 | 10.5 |
| 16 | 6713 | 23 | 10 | 12.2 |
| 17 | 6942 | 44 | 10.4 | 12.0 |
| 18 | 2756 | 46 | 8.2 | 10.0 |
| 19 | 5585 | 38 | 9.6 | 11.0 |
| 20 | 7293 | 35 | 10 | 11.8 |
| 21 | 5007 | 47 | 8.0 | 9.5 |
| 22 | 728 | 41 | 9.0 | 10.2 |
| 23 | 4927 | 33 | 11.0 | 11.9 |
| 24 | 6610 | 36 | 11.2 | 12.1 |
| 25 | 8665 | 37 | 8.3 | 10.2 |
| 26 | 8404 | 42 | 9.3 | 11.7 |
| 27 | 5582 | 42 | 10.5 | 12.0 |
| 28 | 320 | 41 | 7.0 | 9.9 |
| 29 | 7497 | 47 | 9.2 | 10.5 |
| 30 | 1397 | 42 | 8.0 | 9.3 |

## BLEEDING TIME AND CLOTTING TIME OF PATIENTS BEFORE AND AFTER TRETAMENT

| S. NO | OP. NO | AGE | BLEEDING TIME Min'Sec'' | | CLOTTING TIME Min'Sec'' | |
|---|---|---|---|---|---|---|
| | | | BT | AT | BT | AT |
| 1 | 4819 | 38 | 3'09'' | 2'10'' | 5'48'' | 4'25'' |
| 2 | 684 | 28 | 2'40'' | 1'12'' | 5'28'' | 5'10'' |
| 3 | 8610 | 48 | 2'10'' | 2'02'' | 4'22'' | 3'56'' |
| 4 | 891 | 37 | 2'36'' | 1'10'' | 4'52'' | 5'25'' |
| 5 | 124 | 23 | 3'21'' | 2'42'' | 4'46'' | 4'16'' |
| 6 | 2768 | 45 | 2'15'' | 1'59'' | 4'11'' | 3'59'' |
| 7 | 8802 | 17 | 2'28'' | 2'09'' | 5'42'' | 4'30'' |
| 8 | 5812 | 28 | 3'36'' | 2'06'' | 3'24'' | 3'20'' |
| 9 | 3196 | 22 | 2'55'' | 2'02'' | 6'10'' | 5'39'' |
| 10 | 1004 | 30 | 1'48'' | 1'12'' | 5'22'' | 5'10'' |
| 11 | 3663 | 44 | 4'29'' | 3'10'' | 6'44'' | 5'27'' |
| 12 | 3797 | 37 | 2'02'' | 1'58'' | 6'42'' | 6'12'' |
| 13 | 8539 | 42 | 2'54'' | 1'45'' | 4'48'' | 4'20'' |
| 14 | 3842 | 37 | 2'10'' | 2'09'' | 3'48'' | 3'15'' |
| 15 | 825 | 45 | 2'18'' | 1'59'' | 4'49'' | 4'25'' |
| 16 | 6713 | 23 | 2'32'' | 2'06'' | 5'27'' | 5'10'' |
| 17 | 6942 | 44 | 2'51'' | 1'46'' | 4'49'' | 4'20'' |
| 18 | 2756 | 46 | 1'28'' | 1'10'' | 4'14'' | 3'59'' |
| 19 | 5585 | 38 | 3'14'' | 2'58'' | 5'40'' | 4'16'' |
| 20 | 7293 | 35 | 2'11'' | 1'44'' | 5'08'' | 4'30'' |
| 21 | 5007 | 47 | 1'48'' | 1'18'' | 5'22'' | 5'32'' |
| 22 | 728 | 41 | 3'08'' | 2'05'' | 5'47'' | 5'16'' |
| 23 | 4927 | 33 | 3'27'' | 2'44'' | 6'02'' | 6'41'' |
| 24 | 6610 | 36 | 2'42'' | 2'15'' | 5'38'' | 5'51'' |
| 25 | 8665 | 37 | 3'26'' | 2'10'' | 4'21'' | 4'20'' |
| 26 | 8404 | 42 | 1'23'' | 1'06'' | 3'28'' | 3'25'' |
| 27 | 5582 | 42 | 2'10'' | 2'11'' | 5'44'' | 5'15'' |
| 28 | 320 | 41 | 4'42'' | 3'10'' | 5'40'' | 4'59'' |
| 29 | 7497 | 47 | 2'15'' | 1'27'' | 4'35'' | 4'30'' |
| 30 | 1397 | 42 | 3'11 | 2'52'' | 4'18'' | 4'21'' |

## LAB INVESTIGATION REPORT OF PATIENTS

| S NO | OP NO | BEFORE TREATMENT | | | | | | AFTER TREATMENT | | | | | | BEFORE TREATMENT | | | AFTER TREATMENT | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | TC | DC | | | ESR | | TC | DC | | | ESR | | SUGAR | UREA | CHOL | SUGAR | UREA | CHOL |
| | | | P | L | E | ½ | 1 | | P | L | E | ½ | 1 | (mg/dl) | (mg/dl) | (mg/dl) | (mg/dl) | (mg/dl) | (mg/dl) |
| 1 | 4819 | 8100 | 52 | 42 | 6 | 8 | 16 | 8300 | 50 | 45 | 5 | 3 | 9 | 94 | 32 | 171 | 96 | 31 | 175 |
| 2 | 684 | 7800 | 64 | 32 | 4 | 18 | 26 | 7800 | 61 | 34 | 5 | 10 | 20 | 86 | 31 | 174 | 88 | 30 | 180 |
| 3 | 8610 | 9100 | 47 | 46 | 7 | 12 | 22 | 9500 | 46 | 48 | 6 | 3 | 10 | 92 | 38 | 196 | 100 | 36 | 199 |
| 4 | 891 | 9600 | 62 | 35 | 3 | 14 | 30 | 9950 | 63 | 34 | 3 | 1 | 2 | 74 | 29 | 160 | 72 | 28 | 158 |
| 5 | 124 | 7000 | 61 | 35 | 4 | 20 | 40 | 7400 | 66 | 30 | 4 | 18 | 38 | 78 | 29 | 166 | 85 | 29 | 160 |
| 6 | 2768 | 8700 | 52 | 42 | 6 | 7 | 11 | 9000 | 50 | 45 | 5 | 4 | 11 | 86 | 30 | 140 | 93 | 32 | 149 |
| 7 | 8802 | 8600 | 46 | 47 | 7 | 9 | 11 | 9200 | 51 | 45 | 4 | 2 | 5 | 81 | 30 | 160 | 85 | 29 | 158 |
| 8 | 5812 | 9150 | 46 | 50 | 4 | 20 | 42 | 9300 | 44 | 52 | 4 | 10 | 22 | 82 | 34 | 144 | 90 | 35 | 152 |
| 9 | 3916 | 7700 | 54 | 43 | 3 | 8 | 18 | 8200 | 57 | 40 | 3 | 4 | 8 | 104 | 33 | 150 | 102 | 31 | 145 |
| 10 | 1004 | 9000 | 56 | 39 | 5 | 26 | 50 | 9250 | 59 | 37 | 4 | 14 | 29 | 112 | 30 | 185 | 110 | 34 | 188 |
| 11 | 3663 | 8200 | 51 | 41 | 8 | 6 | 13 | 8800 | 53 | 43 | 4 | 8 | 17 | 78 | 27 | 169 | 81 | 29 | 165 |
| 12 | 3797 | 9600 | 57 | 39 | 4 | 25 | 50 | 9600 | 69 | 29 | 2 | 8 | 19 | 73 | 36 | 180 | 80 | 38 | 181 |
| 13 | 8539 | 8300 | 49 | 46 | 5 | 10 | 20 | 9650 | 48 | 47 | 5 | 2 | 5 | 81 | 38 | 180 | 95 | 40 | 178 |
| 14 | 3842 | 8500 | 61 | 31 | 8 | 14 | 28 | 8600 | 65 | 34 | 1 | 3 | 11 | 108 | 35 | 171 | 104 | 32 | 170 |
| 15 | 825 | 6100 | 53 | 40 | 7 | 12 | 23 | 7350 | 58 | 38 | 4 | 4 | 8 | 94 | 27 | 193 | 101 | 29 | 191 |

TC: TOTAL COUNT DC: DIFFERENTIAL COUNT ESR: ERYTHROCYTE SEDIMENTATION RATE

CHOL : CHOLESTROL

| S NO | OP NO | BEFORE TREATMENT | | | | | | AFTER TREATMENT | | | | | | BEFORE TREATMENT | | | AFTER TREATMENT | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | TC | DC | | | ESR | | TC | DC | | | ESR | | SUGAR | UREA | CHOL | SUGAR | UREA | CHOL |
| | | | P | L | E | ½ | 1 | | P | L | E | ½ | 1 | (mg/dl) | (mg/dl) | (mg/dl) | (mg/dl) | (mg/dl) | (mg/dl) |
| 16 | 6713 | 9400 | 60 | 34 | 6 | 10 | 20 | 9800 | 64 | 33 | 3 | 1 | 2 | 81 | 38 | 180 | 92 | 37 | 176 |
| 17 | 6942 | 8200 | 57 | 39 | 4 | 12 | 25 | 8300 | 59 | 38 | 3 | 1 | 3 | 99 | 32 | 162 | 97 | 35 | 165 |
| 18 | 2756 | 9400 | 62 | 35 | 3 | 9 | 20 | 9900 | 63 | 36 | 1 | 4 | 9 | 82 | 29 | 173 | 91 | 28 | 179 |
| 19 | 5585 | 8800 | 61 | 33 | 6 | 15 | 32 | 9100 | 60 | 36 | 4 | 2 | 6 | 89 | 30 | 148 | 111 | 27 | 155 |
| 20 | 7293 | 7200 | 48 | 47 | 5 | 12 | 27 | 7550 | 56 | 41 | 3 | 1 | 4 | 92 | 29 | 144 | 96 | 30 | 150 |
| 21 | 5007 | 8900 | 60 | 37 | 3 | 10 | 20 | 9100 | 65 | 32 | 3 | 9 | 17 | 110 | 27 | 178 | 115 | 29 | 172 |
| 22 | 728 | 9150 | 59 | 36 | 5 | 8 | 17 | 9300 | 55 | 41 | 4 | 4 | 8 | 99 | 31 | 143 | 90 | 34 | 150 |
| 23 | 4927 | 9000 | 53 | 43 | 4 | 2 | 5 | 9650 | 58 | 41 | 1 | 1 | 2 | 70 | 34 | 151 | 83 | 30 | 147 |
| 24 | 6610 | 9700 | 53 | 44 | 3 | 7 | 36 | 9700 | 50 | 48 | 2 | 1 | 2 | 101 | 36 | 171 | 109 | 34 | 172 |
| 25 | 8665 | 8900 | 50 | 44 | 6 | 8 | 19 | 9100 | 51 | 43 | 6 | 3 | 8 | 73 | 23 | 155 | 71 | 25 | 152 |
| 26 | 8404 | 6000 | 58 | 39 | 3 | 10 | 18 | 6400 | 56 | 41 | 3 | 2 | 3 | 95 | 28 | 167 | 100 | 29 | 166 |
| 27 | 5582 | 9900 | 58 | 36 | 6 | 4 | 9 | 9700 | 61 | 34 | 5 | 1 | 2 | 88 | 39 | 183 | 82 | 36 | 180 |
| 28 | 320 | 9000 | 48 | 47 | 5 | 31 | 28 | 9150 | 60 | 39 | 1 | 5 | 12 | 90 | 34 | 152 | 112 | 35 | 153 |
| 29 | 7497 | 8300 | 66 | 27 | 7 | 13 | 55 | 8700 | 66 | 30 | 4 | 4 | 10 | 118 | 35 | 184 | 99 | 33 | 190 |
| 30 | 1379 | 7800 | 57 | 39 | 4 | 20 | 33 | 8000 | 59 | 38 | 3 | 10 | 20 | 98 | 29 | 172 | 94 | 31 | 170 |

TC: TOTAL COUNT DC: DIFFERENTIAL COUNT ESR: ERYTHROCYTE SEDIMENTATION RATE

CHOL : CHOLESTROL

# DISCUSSION

# DISCUSSION

**PERUMBADU ROGAM** has been compared with the modern clinical entity **MENORRHAGIA.** Menstrual disorders are the second most common gynaecological condition to be referred to hospitals. Among the menstrual disorders MENORRHAGIA is the most common gynaecological disorder in the reproductive system of women. Around 30% of women reports heavy menstrual bleeding.

Most common causes of Menorrhagia are Dysfunctional uterine bleeding, Fibroid uterus, endometrial polyp, poly cystic ovarian disease, Adenomyosis and chronic tubo-ovarian mass. Long duration of menstrual blood flow, passage of blood clots, use of increased number of sanitary pads, pallor and low level of haemoglobin give an idea about the correct diagnosis and magnitude of menorrhagia.

Menorrhagia interferes with a Women's physical, emotional, social and mental quality of life. It can occur alone or in combination with other symptoms. It is related to increased limitations in physical activities and limitations in social and leisure activities.

The definitive treatment is appropriate to the cause for Menorrhagia. Hence with the help of the trial medicine from the Siddha System of medicine, results and observations are noted for this study.

30 patients with Menorrhagia were selected. The patients were examined based on Siddha and as well as modern aspects. All the necessary investigations were made for all patients during the study. All the patients were administrated with the trial medicine.

The clinical improvements of the patients were completely observed and efficacy of the trial medicine has been studied. Results obtained were discussed below for better conclusion.

Trial drug administered was Maampisin Chooranam – 2 gm thrice a day after food for 15 days for 3 consecutive cycles.

**DRUG AUTHENTICATION**

The required raw drugs were obtained from a well reputed indigenous raw drug shop. The raw drugs taken for study were authenticated by the botanist, Siddha Central Research Institute, Chennai.

**PRE CLINICAL STUDIES**

**PHYSIOCHEMICAL ANALYSIS**

The Loss on drying (at 105° C) was 6.67 %

The total ash value was 3.26 %

The water soluble ash value was 1.92 %

The acid insoluble ash value was less than 1 %

Water soluble extractive value was 36.65 %

Alcohol soluble extractive value was 21.72 %

**TOXICOLOGICAL STUDY**

**ACUTE TOXICITY STUDY**

Acute toxicity study of the trial medicine Maampisin Chooranam was carried out as per OECD guideline (Organization for Economic Co-operation and Development) Guideline-423. The experimental protocol was approved by The Institutional Animal Ethics Committee of C.L.Baid Metha College of Pharmacy, Chennai, Tamil Nadu, India. IAEC reference number : LI/15/CLBMCP/2017. The study was conducted with single oral dose administration of Maampisin Chooranam. In acute toxicity test the Maampisin Chooranam was found to be non-toxic at the dose level of 2000mg/kg body weight

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**SUB-ACUTE TOXICITY STUDY**

Sub-acute toxicity study was carried out for 28 days as per OECD guidelines – 407. The animals were randomly divided into control group and drug treated groups for low and high doses. At the end of the studies the animals were sacrificed and the haematological parameters, biochemical parameters, urine parameters and the histopathology of the vital organs like brain, heart, liver, lung and kidney were carried

out. The study results show that the trial medicine was safe, and did not produced any toxic effects.

**PHARMACOLOGICAL EVALUATION**

The experimental protocol was approved by The Institutional Animal Ethics Committee of C.L.Baid Metha College of Pharmacy, Chennai, Tamil Nadu, India. IAEC: LI/15/CLBMCP/2017. Pharmacological Evaluation of styptic activity of Maampisin Chooranam on Adrenochrome induced bleeding time prolongation in rats. The result shows that the trial medicine Maampisin Chooranam has styptic activity.

**BIOCHEMICAL ANALYSIS**

In Maampisin Chooranam, basic radicals like iron, Phosphate and reducing sugar were present.

**CLINICAL STUDIES**

**STUDY DESIGN**

A clinical trial on PITHA PERUMBADU ROGAM was conducted at the OPD section of POST GRADUATE, POTHU MARUTHUVAM DEPARTMENT attached to ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE, Chennai-106, during the period 2016-2018.

**IEC AND CTRI APPROVAL**

The study was approved by Institutional Ethics Committee (IEC) and the approved number is GSMC-CH-ME-5/003/2016. The study was registered in Clinical Trials Registry – India (CTRI) and the CTRI number is CTRI/2018/03/012381.

**SAMPLE SIZE**

30 patients

**AGE DISTRIBUTION**

Women with the reproductive age 15-50 were affected with the disease. 40% of Patients in the age group of 36-45 years were mostly affected, 37% of patients were in the age group of 46-50 years. 13% of patients were in the age group of 15-25, 10% of patients were in the age group of 26-35 Years.

High incidences of cases were noted in age ranging of 36-45 years during the studies. The disease is more common in perimenopausal stage which is usually begins in the age of 40 years.

**OCCUPATIONAL STATUS**

63% of patients were house wife, 30% of patients were working women and 7% of patients were students.

**SOCIO-ECONOMIC STATUS**

43% of patients were from lower income group, 40% of patients were middle income group and 17% of patients were from lower income group. Heavy menstrual bleeding is mainly concerned with low progesterone level and it is generally common in women from low income group who are mostly anaemic due to decreased intake of healthy foods.

**FOOD HABITS**

57% of patients had vegetarian diet and 43% of patients had mixed diet habit. Non-vegetarian diet helps in maintaining fairly consistent levels of progesterone which results in regular menstrual cycles whereas vegetarian diet leads to considerable reductions in progesterone.

**DISTRIBUTION OF LANDSCAPES (THINAI)**

As the trial was conducted in Chennai which is Neithal nilam, most of patients about 97% were from Neithal Nilam and 3% of patients were from Marutha Nilam.

Neithal nilam is more prone to Pitha disease. Perumbadu Rogam is mostly caused by the derangement of Pitha Kuttram.

**SEASONAL REFERENCE**

60% of patients were reported in Pinpani kaalam and 40% of patients were reported in Munpani kaalam.

**OBSERVATION OF ALTERED MUKKUTRAM**

In Perumbadu, the clinical condition is due to the imbalance of PITHAM. Pitham is deranged primarily and later it deranges Vatha and the derangement of Pitha-vatha leads to the derangement of Abanaan which in turn cause the disease. The pathogenesis of the disease depends upon the affected Pitha and Vatha.

**VATHAM**

Abaanan (100%), Pranan (20%),Udhanan (10%), Viyanan (100%), Koorman (7%), Samanan (40%), and Devathathan (100)% were affected.

- Affected Abaanan results in causing excessive and prolonged menstruation bleeding.
- Affected Pranan results in causing dyspnoea and breathlessness due to low Hb level.
- Affected Viyanan results in causing lower abdominal pain and low back ache headache and body pain.
- Affected Udhanan results in producing nausea, vomiting and cough.
- Affected Koorman results in causing visual disturbances..
- Affected Samaanan and Devathathan results in producing loss of appetite or indigestion and tiredness respectively.

**PITHAM**

Saathagam (100%), Ranjagam (100%), Alosagam (7%), Praasagam (90%) and Analagam (97%) were affected.

- Affected Saathaga Pitham results in causing general malaise, tiredness and giddiness.
- Affected Ranjaga pitham results in low Hb level.
- Affected Praasagam results in pallor of skin due to very low level of haemoglobin.
- Affected Aalosaga pitham results in producing dimness of vision.
- Affected Analaga Pitham results in causing loss of appetite or indigestion.

**KABHAM**

Kilethagam ( 40%), Tharpagam (10%), Santhigam (67%) were affected. .

- Affected Santhigam results in producing low back ache.

- Affected Kilethagam results in causing loss of appetite.
- Affected Tharpagam results in producing burning sensation.

**EZHU UDAL THATHUKKAL**

Saaram (100%), Senneer (100%), Enbu(67%), Suronitham (100%) were affected.

- Affected Saaram results in causing loss of appetite and tiredness.
- Affected Senneer results in causing decreased level of haemoglobin in blood.
- Affected Enbu results in causing Low back ache.
- Affected Suronitham results due to presence of excessive menstruation.

**ENVAGAI THERVUGAL**

Among 30 patients, Naa (90%), Niram (50%), Vizhi (97%), Malam (20%), Moothiram (10%) and Naadi (100%) were affected. Pitha vatha naadi (63%) and Vatha pitha naadi (37%).

- Affected Naa results in pallor of tongue.
- Affected Niram results in pallor of the skin due to low Hb level.
- Affected Vizhi results in paleness of lower eyelids due to low level of haemoglobin.
- Affected Malam was due to constipation.
- Affected Moothiram was due to burning micturation.

**NAADI**

Pitha vatha naadi (65%) and Vatha Pitha naadi (35%) were noticed.

As per Siddha classical literature, Perumbadu Rogam occurs due to derangement of Pitha Naadi and Vatha naadi.

**NEIKURI**

Pitha neer (77%) and vatha neer (23%) was observed.

Perumbadu is a Pitha reflected disease, so most of the patients had Pith neer.

**HAEMATOLOGICAL FINDINGS**

Blood routines were sampled. It was observed that 100% of patients show elevation of haemoglobin level in blood. Bleeding time and clotting time investigation was taken for affordable patients to exclude blood disorders.

**SPECIAL INVESTIGATION**

USG Abdomen and pelvis was taken before the treatment. The impression found on USG pelvis was Fibroid uterus, poly cystic ovarian disease and bulky uterus in most of the cases. After confirming the results, the patients were given the trial medicine Maampisin chooranam and instructed to follow the diet and other restriction based on Siddha System.

**MODE OF ACTION OF THE DRUG MAAMPISIN CHOORANAM**

**BASED ON TASTE (SUVAI)**

In the trial medicine Maampisin Chooranam - most of the ingredients included in this trial medicine were thuvarppu and inippu suvai. Basically astringent taste has the characteristic action of:

- Treats the derangement of pitham
- Causes vaso constriction
- Decreases the secretions
- Purifies the blood
- Cures the ulcer  Basically bitter taste has the following characteristics:
- Treats the derangement of Pitham.
- Cures loss of appetite.
- Removes toxins from body.

Basically sweetness taste has the following characteristics:

- Treats the derangement of Pitham.
- Nourishes the body

By this, the trial medicine Maampisin Chooranam treats the derangement of pitha which is the main cause of disease and also controls bleeding by vaso constriction. Hence it acts as an effective drug in Pitha Perumbadu Rogam and considered to be Ethirurai maruthuvam.

**BASED ON NATURE (VEERIYAM)**

The trial medicine Maampisin Chooranam is of Thatpam nature as the ingredients in this is coolant in nature.

## CLINICAL MANIFESTATION

Clinical symptoms before and after treatment were noted. All the patients were given score based on Pictorial Blood Loss Assessment Chart (PBAC). The before and after treatment score range is taken as improvement.

Thus the clinical trial study showed significant clinical improvements in certain clinical manifestations of Pitha Perumbadu Rogam. Numbers of pads and Number of days of menstrual cycle in the patients who had prolonged menstruation were decreased due to reduction of increased menstrual blood flow.

Haemoglobin level of blood is elevated in all the patients. Since, the ingredients present in the trial medicine have haematinic activity.

## BIO STATISTICAL ANALYSIS

Statistical analysis of clinical study before and after treatment was done for subjective and objective parameters ( no of pads, menstrual blood loss assessment score, bleeding time, clotting time, haemoglobin level). Since the p value (< .0001) is highly significant it can be concluded that the treatment for Pitha Perumbadu shows improvement in HB level among the patients and reduction in number of pads, menstrual blood flow, bleeding time, clotting time.

## GRADING OF RESULTS

Out of 30 patients, 21 cases (70%) shows good result, 6 cases (20%) shows moderate result and 3 cases (10%) shows mild result.

# SUMMARY

# SUMMARY

The clinical study on PITHA PERUMBADU ROGAM was carried out in Post graduate department of Maruthuvam, Government Siddha Medical College, Arignar Anna Government Hospital, Chennai - 106 during the period of 2016 - 2018.

A total of 30 patients were treated in the Outpatient department. The clinical and pathological assessment was carried out on the basis of Siddha and Modern aspects. All the patients were treated with MAAMPISIN CHOORANAM (2 gm tds). The duration of the treatment was fixed as 1 to 15 Days of menstruation for 3 consecutive cycles.

- The comparatively larger incidence of Pitha Perumbadu was found to be in 36-45 years of age.
- The prevalence of the disease was high among low class populations 43% followed by Middle class 40% and Lower class population 17%.
- Out of 30 patients, 2 patients (7%) were student, 9 patients (30%) were Office going people, 19 patients (63%) were house wife.
- Among dietary patterns, 17 patients (57%) consume vegetarian diet.
- From selected 30 patients, 12 patients (40%) come under Munpani kaalam and 18 patients (60%) come under Pinpani Kaalam.
- Out of 30 patients, 97% comes under Neithal category.
- In Mukkutram aspect - In Vatham

  Abanan (100%), Pranan (20%), Viyanan (100%), Koorman (7%), Samanan (40%) and Devathathan (100)% were affected.

- In pitham

  Sathagam (100%), Ranjagam (100%), Alosagam (7%), Praasagam (90%) and Analagam (40%) were affected.

- In Kapham

  Kilethagam (40%), Tharpagam (10%), Santhigam (67%) were affected.

- Among Ezhu Udal Thathukkal, Saaram (100%), Senneer (100%), Enbu (67%), Suronitham (100%) were affected.

- Among Envagai Thervugal Naa (90%), Niram (50%), Vizhi (97%), Malam (20%), Moothiram (3%), Naadi (100%) were affected.
- Naadi showed Pitha vatha naadi (63%) and Vatha pitha naadi (37%).
- In Neikuri examination Pitha neer (77%) and vatha neer (23%) were seen.
- The ingredients of trial medicines were found to have the properties of reducing the symptoms of PITHA PERUMBADU ROGAM. In Maampisin Chooranam, basic radicals like phosphate, iron and reducing sugar were present.
- The Toxicological studies of the trial medicine reveal no toxicity.
- The Pharmacological studies of the trial medicine shows styptic activity.
- The Bio statistical report of the clinical trial shows significant P value <0.001 and concluded that, the treatment is effective and significant.
- Among 30 patients, 70% of cases showed good result and 20% of cases showed moderate result and 10% of cases showed mild result in PITHA PERUMBADU ROGAM (MENORRHAGIA).

# CONCLUSION

# CONCLUSION

- Pitha Perumbadu is primarily due to the derangement of Pitha kuttram.
- The trial medicine Maampisin Chooranam predominating with Thuvarppu suvai, it neutralizes the deranged pitham by Ethirurai Maruthuvam
- From the preclinical toxicity studies, the medicine Maampisin Chooranam revealed no toxicity and proved to be safe.
- From the preclinical pharmacological studies, it is evident that the medicine Maampisin Chooranam has Styptic activity.
- No adverse effects were reported during the course of the treatment.
- The medicine Maampisin Chooranam which gives a maximum relief in symptoms of Menorrhagia.
- The ingredients of the trial medicine are easily available.
- The trial medicine is economical.

Therefore I conclude that, the medicine Maampisin Chooranam can give a better solution for Pitha Perumbadu.

# ANNEXURES

The Tamil Nadu Dr.M.G.R.Medical University

69, Anna Salai, Guindy, Chennai - 600 032.

*This Certificate is awarded to Dr/Mr/Mrs.....* A. DHIVYA BHARATHI .....

*For participating as ~~Resource~~ ~~Person~~ / Delegate in the Twentieth Workshop on*

**"RESEARCH METHODOLOGY & BIOSTATISTICS"**

*For **AYUSH Post Graduates & Researchers***

*Organized by the Department of Siddha*

*The Tamil Nadu Dr. M.G.R. Medical University From 07th to 11th March 2016.*

**Dr.N.KABILAN,** M.D.(S)
PROF & HEAD
DEPT.OF SIDDHA

Prof.**Dr.P.ARUMUGAM,** M.D.,
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01.06.2017

**AUTHENTICATION CERTIFICATE FOR 17051717-19**

Certified that the drugs submitted by Dr. A. Dhivyabharathi, MD(S) II Year, Dept of Maruthuvam, Govt. Siddha Medical College, Arumbakkam, Chennai-106 are identified as:

| SN | Botanical Name | Tamil Name | Part | Code |
|---|---|---|---|---|
| 1. | *Phyllanthes emblica* L. | Nellivatral | Fruit | P17051717A |
| 2. | *Mangifera indica* L. | Mampisin | Pisin | M17051718I |
| 3. | *Borassus flabellifer* L. | Panangarkandu | Sugar | B17051719F |

P17051717A M17051718I B17051719F

01/06/17.

**Dr. K.N. Sunil Kumar**
R.O. Pharmacognosy

**Dr. P. Sathiya Rajeswaran**
Assistant Director (Siddha) I/C
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डॉ. पी. सत्यिराजेश्वरण/Dr. P. Sathiyarajeswaran

**C.L.BAID METHA COLLEGE OF PHARMACY**

**(An ISO 9001-2000 certified institute)**

**Jyothi Nagar, Old Mahabalipuram Road**

**Thoraipakkam, Chennai – 600 097**

## CERTIFICATE

This is to certify that the project entitled, Pharmacological and Toxicological screening of Maampisin chooranam submitted in partial fulfilment for the degree of M.D.(siddha) was carried out at C.L.Baid Metha college of Pharmacy, Chennai-97 in the Department of Pharmacology during the academic year of 2017-2018. It has been approved by the IAEC No: LI/15/CLBMCP/2017

C.L.Baid Metha College of Pharmacy CHENNAI-97 Thoraipakkam

Dr.P. MURALIDHARAN

IAEC MEMBER SECERATARY

# ACUTE ORAL TOXICITY STUDY OF MAAMPISIN CHOORANAM (OECD GUIDELINE – 423)

**Introduction:**

- The acute toxic class method is a stepwise procedure with the use of 3 animals of a single sex per step.
- Depending on the mortality and/or the moribund status of the animals, on average 2-4 steps may be necessary to allow judgment on the acute toxicity of the test substance.
- This procedure is reproducible, uses very few animals and is able to rank substances in a similar manner to the other acute toxicity testing methods.
- The acute toxic class method is based on biometric evaluations with fixed doses, adequately separated to enable a substance to be ranked for classification purposes and hazard assessment.
- In principle, the method is not intended to allow the calculation of a precise LD50, but does allow for the determination of defined exposure ranges where lethality is expected since death of a proportion of the animals is still the major endpoint of this test.
- The method allows for the determination of an LD50 value only when at least two doses result in mortality higher than 0% and lower than 100%.
- The use of a selection of pre-defined doses, regardless of test substance, with classification explicitly tied to number of animals observed in different states improves the opportunity for laboratory to laboratory reporting consistency and repeatability.

**Principle of the Test:**

It is the principle of the test that based on a stepwise procedure with the use of a minimum number of animals per step, sufficient information is obtained on the acute toxicity of the test substance to enable its classification. The substance is administered orally to a group of experimental animals at one of the defined doses.

The substance is tested using a stepwise procedure, each step using three animals of a single sex. Absence or presence of compound-related mortality of the animals dosed at one step will determine the next step, i.e.

- no further testing is needed
- dosing of three additional animals, with the same dose
- dosing of three additional animals at the next higher or the next lower dose level. The method will enable a judgment with respect to classifying the test substance to one of a series of toxicity classes.

**Methodology:**

**Selection of Animal Species**

The preferred rodent species is the wistar albino rat, although other rodent species may be used. Healthy young adult animals are commonly used laboratory strains should be employed. Females should be nulliparous and non-pregnant. Each animal, at the commencement of its dosing, should be between 6 to 8 weeks old and the weight (150-200gm) should fall in an interval within±20 % of the mean weight of any previously dosed animals.

**Housing and Feeding Conditions**

The temperature in the experimental animal room should be 22ºC + 3ºC. Although the relative humidity should be at least 30% and preferably not exceed 70% other than during room cleaning the aim should be 50-60%. Lighting should be artificial, the sequence being 12 hours light, 12 hours dark. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water. Animals may be group-caged by dose, but the number of animals per cage must not interfere with clear observations of each animal.

**Preparation of animals:**

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions.

**Test Animals and Test Conditions:**

Sexually mature Female Wistar albino rats (150-200gm) were obtained from Kings institute, Chennai. All the animals were kept under standard environmental

condition (22±3°C). The animals had free access to water and standard pellet diet (Sai meera foods, Bangalore).

**Preparation of animals:** The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

**Preparation for Acute Toxicity Studies**

Rats were deprived of food overnight (but not water 16-18 h) prior to administration of the **MAAMPISIN CHOORANAM**

The principles of laboratory animal care were followed and the Institutional Animal Ethical Committee approved the use of the animals and the study design
IAEC No: LI/15/CLBMCP/2017

| | |
|---|---|
| **Test Substance** | : **MAAMPISIN CHOORANAM** |
| **Animal Source** | : Kings institute, Chennai. |
| **Animals** | : Wister Albino Rats (Female-3+3) |
| **Age** | **:** >6 weeks |
| **Body Weight on Day 0** | **:**180-280 gm. |
| **Acclimatization** | **:** Seven days prior to dosing. |
| **Veterinary examination** | **:** Prior and at the end of the acclimatization period. |
| **Identification of animals** | **:** By cage number, animal number and individual marking by using Picric acid. |
| **Number of animals** | : 3 Female/group, |
| **Route of administration** | : Oral |

**Diet** **:** Pellet feed supplied by Sai meera foods Pvt Ltd,Bangalore

**Water** **:** Aqua guard portable water in polypropylene bottles

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**Housing & Environment** **:** The animals were housed in Polypropylene cages provided with bedding of husk.

**Housing temperature** **:** between 22ºC $\pm$ 3ºC.

**Relative humidity** **:** between 30% and 70%,

**Air changes** **:** 10 to 15 per hour and

**Dark and light cycle** **:** 12**:**12 hours.

**Duration of the study** **:** 14 Days

**Administration of Doses:**

**MAAMPISIN CHOORANAM** was suspended in water and administered to the groups of wistar albino rats in a single oral dose by gavage using a feeding needle. The control group received an equal volume of the vehicle. Animals were fasted 12 hours prior to dosing. Following the period of fasting, the animals were weighed and then the test substance was administered. Three Female animals are used for each group. The dose level of 3, 30, 300 and 2000 mg/kg body weight was administered stepwise. After the substance has been administered, food was withheld for a further 3-4 hours. The principle of laboratory animal care was followed. Observations were made and recorded systematically and continuously as per the guideline after substance administration. The visual observations included skin changes, mobility, aggressively, sensitivity to sound and pain, as well as respiratory movements. Finally, the number of survivors was noted after 24 hours and these animals were then monitored for a further 14 days and observations made daily. The toxicological effect was assessed on the basis of mortality.

**Observations:**

Animals are observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours, and daily thereafter, for a total of 14 days, except where they need to be removed from the study and humanely killed for animal welfare reasons or are found dead. It should be determined by the toxic reactions, time of onset and length of recovery period, and may thus be extended when considered necessary. The times at which signs of toxicity appear and disappear are important, especially if there is a tendency for toxic signs to be delayed. All observations are systematically recorded with individual records being maintained for each animal.

Observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor activity and behavior pattern. Attention was directed to observations of

tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. The principles and criteria summarized in the Humane Endpoints Guidance Document taken into consideration. Animals found in a moribund condition and animals showing severe pain or enduring signs of severe distress was humanly killed. When animals are killed for human reasons or found dead, the time of death was recorded.

**Acute oral toxicity study of MAAMPISIN CHOORANAM**

**Table 1: Dose finding experiment and its behavioral signs of acute oral Toxicity**

**Observation done:**

| SL | Group CONTROL | Observation | SL | Group TEST GROUP | Observation |
|---|---|---|---|---|---|
| 1 | Body weight | Normal | 1 | Body weight | Normally increased |
| 2 | Assessments of posture | Normal | 2 | Assessments of posture | Normal |
| 3 | Signs of Convulsion Limb paralysis | Normal | 3 | Signs of Convulsion | Absence of sign (-) |
| 4 | Body tone | Normal | 4 | Body tone | Normal |
| 5 | Lacrimation | Normal | 5 | Lacrimation | Absence |
| 6 | Salivation | Normal | 6 | Salivation | Absence |
| 7 | Change in skin color | No significant color change | 7 | Change in skin color | No significant color change |
| 8 | Piloerection | Normal | 8 | Piloerection | Normal |
| 9 | Defecation | Normal | 9 | Defecation | Normal |
| 10 | Sensitivity response | Normal | 10 | Sensitivity response | Normal |
| 11 | Locomotion | Normal | 11 | Locomotion | Normal |
| 12 | Muscle gripness | Normal | 12 | Muscle gripness | Normal |
| 13 | Rearing | Mild | 13 | Rearing | Mild |
| 14 | Urination | Normal | 14 | Urination | Normal |

**Behavior:**

The animals will be observed closely for behavior in the first four hours which includes abnormal gait, aggressiveness, exophthalmos, ptosis, akinesia, catalepsy, convulsion, excitation, head twitches, lacrimation, loss of corneal reflex, loss of traction, piloerection reactivity of touch, salivation, scratching, sedation, chewing, head movements, sniffing, straub, tremor and writhes, diarrhea, leathery, sleep and coma.

**Body Weight:**

Individual weight of animals was determined before the test substance was administered and weights will be recorded at day 1, 7, and 14 of the study. Weight changes were calculated and recorded. At the end of the test, surviving animals were weighed and humanly killed.

**Food and water Consumption:**

Food and water consumed per animal was calculated for control and the treated dose groups.

**Mortality:**

Animals were observed for mortality throughout the entire period.

**Results:**

All data were summarized in tabular form, (Table-1-4) showing for each test group the number of animals used, the number of animals displaying signs of toxicity, the number of animals found dead during the test, description of toxic symptoms, weight changes, food and water intake.

No of animals in each group:3

**Table 2 (Observational study Results)**

| No | Dose mg/kg | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | Control | + | - | - | + | - | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 2. | 2000 mg/kg | + | - | - | + | - | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - |

1..Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15.Lacrimation 16. Exophthalmos 17. Diarrhea 18. Writhing

19. Respiration 20. Mortality.

(+ Present, - Absent)

**Table 3( Body weight Observation)**

| DOSE | DAYS | | |
|---|---|---|---|
| | 1 | 7 | 14 |
| **CONTROL** | 166.6± 1.95 | 168.2± 4.82 | 169.2 ± 3.12 |
| **2000 mg/kg** | 172.3± 2.18 | 174.2± 1.26 | 177.2 ± 3.27 |
| **P value (p)*** | NS | NS | NS |

**Table 4 (Water intake (ml/day) of Wistar albino rats group exposed to (MAAMPISIN CHOORANAM*):***

| DOSE | DAYS | | |
|---|---|---|---|
| | 1 | 6 | 14 |
| **CONTROL** | 32.5 ± 1.34 | 33.0± 10.13 | 32.4± 3.13 |
| **2000 mg/kg** | 29.4±2.33 | 30.6±1.91 | 30.9± 2.19 |
| **P value (p)*** | NS | NS | NS |

N.S- Not Significant,**(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

**Table 5: Food intake (gm/day) of Wistar albino rats group exposed to MAAMPISIN CHOORANAM**

| DOSE | DAYS | | |
|---|---|---|---|
| | 1 | 7 | 14 |
| **CONTROL** | 25.16±6.36 | 27.60±3.12 | 27.61±5.46 |
| **2000 mg/kg** | 27.42±1.64 | 28.31±3.22 | 28.12±6.14 |
| **P value (p)*** | NS | NS | NS |

**REPEATED DOSE 28-DAY ORAL TOXICITY STUDY OF MAAMPISIN CHOORANAM**

**Test Substance** : **MAAMPISIN CHOORANAM**

**Animal Source** : TANUVAS,Madhavaram, Chennai.

**Animals** : Wister Albino Rats (Male -24, and Female-24)

**Age** **:** >6 weeks

**Body Weight** **:**160-180 gm.

**Acclimatization** **:** Seven days prior to dose.

**Veterinary examination** **:** Prior and at the end of the acclimatization period.

**Identification of animals** **:** By cage number, animal number and individual marking by using Picric acid

**Diet** **:** Pellet feed supplied by Sai meera foods Pvt Ltd, Bangalore

**Water** **:** Aqua guard portable water in polypropylene bottles.

**Housing & Environment** **:** The animals were housed in Polypropylene cages provided with bedding of husk.

**Housing temperature** **:** between 22ºC ± 3ºC.

**Relative humidity** **:** between 30% and 70%,

**Air changes** **:** 10 to 15 per hour

**Dark and light cycle** **:** 12**:**12 hours.

**Duration of the study** **:** 28 Days.

**Table 5**

| **Groups** | | **No of Rats** |
|---|---|---|
| Group I - Control | Vehicle control (Normal Saline ) | 12(6male,6 female) |
| Group II - Low Dose | Maampisin Chooranam 20 Mg/Kg | 12 (6male,6 female) |
| Group III - Mid Dose | Maampisin Chooranam 100 Mg/Kg | 12 (6male,6female) |
| Group IV – High Dose | Maampisin Chooranam 200 Mg/Kg | 12(6male,6female) |

**Methodology**

**Randomization, Numbering and Grouping of Animals:**

48 Wistar Albino Rats (24M + 24F) were selected and divided into 4 groups. Each group consist of 12 animals (Male -6, and Female-6). First group treated as a control and other three group were treated with test drug (low, mid, high) for 28 days. Animals were allowed acclimatization period of 7 days to laboratory conditions prior to the initiation of treatment. Each animal was marked with picric acid. The females were nulliparous and non-pregnant.

**Justification for Dose Selection:**

As per OECD guideline three dose levels were selected for the study. They are low dose (20 mg/kg), mid dose dose (100 mg/kg), high dose (200 mg/kg). X is calculated by multiplying the dose (2000mg/kg) i.e X dose is 20 mg/kg/animal ,5Xmid dose is 100 mg/kg, 10X high dose is 200 mg/kg.

**Preparation and Administration of Dose:**

MAAMPISIN CHOORANAM is suspended in water, It was administered to animals at the dose levels of 20, 100 and 200 mg/kg. The test substance suspensions were freshly prepared every two days once for 28 days. The control animals were administered vehicle only. The drug was administered orally by using oral gavage once daily for 28 consecutive days.

**Observations:**

**Experimental animals were kept under observation throughout the course of study for the following:**

**Body Weight:**

Weight of each rat was recorded on day 0, at weekly intervals throughout the course of study.

**Food and water Consumption:**

Food and water consumed per animal was calculated for control and the treated dose groups.

**Clinical signs**:

All animals were observed daily for clinical signs. The time of onset, intensity and duration of these symptoms, if any, were recorded.

**Mortality:**

All animals were observed twice daily for mortality during entire course of study.

**Necropsy:**

All the animals were sacrificed by excessive anaesthesia on day 29. Necropsy of all animals was carried out.

**Laboratory Investigations:**

Following laboratory investigations were carried out on day 29 in animals fasted over-night. Blood samples were collected from orbital sinus using sodium heparin (200IU/ml) for Bio chemistry and potassium EDTA (1.5 mg/ml) for Hematology as anticoagulant. Blood samples were centrifuged at 3000 r.p.m. for 10 minutes.

**Haematological Investigations:**

Haematological parameters were determined using Haematology analyzer.

**Biochemical Investigations:**

Biochemical parameters were determined using auto-analyzer.

**Histopathology:**

Control and highest dose group animals will be initially subjected to histopathological investigations. If any abnormality found in the highest dose group than the low, then the mid dose group will also be examined. Organs will be collected from all animals and preserved in 10% buffered neutral formalin for 24 h and washed in running water for 24 h. The organ sliced 5 or 6µm sections and were dehydrated in an auto technicon and then cleared in benzene to remove absolute alcohol. Embedding was done by passing the cleared samples through three cups containing molten paraffin at 50°C and then in a cubical block of paraffin made by the "L" moulds. It was followed by microtome and the slides were stained with Haematoxylin-eosin red.

**Statistical analysis:**

Findings such as body weight changes, water and food consumption, hematology and blood chemistry were subjected to One-way ANOVA followed by dunnett test using a computer software programme – Graph pad version 5.0 .All data were summarized in tabular form, (Table-6 to 12)

**RESULTS**

**Repeated Dose 28- day oral toxic study of MAAMPISIN CHOORANAM**

**Table 6: Body weight of wistar albino rats group exposed to MAAMPISIN CHOORANAM**

| DOSE | DAYS | | | | |
|---|---|---|---|---|---|
| | 1 | 7 | 14 | 21 | 28 |
| **CONTROL** | 172.0± 4.23 | 172.4 ± 3.42 | 174.7 ± 1.36 | 174.2 ± 1.33 | 175.7 ± 1.31 |
| **LOW DOSE** | 171.2 ± 3.12 | 172.7 ± 4.64 | 175.4± 3.18 | 175.8 ± 1.86 | 176.12± 2.36 |
| **MID DOSE** | 178.6± 1.34 | 179.3 ± 2.14 | 180.4 ± 6.32 | 182.1 ± 3.16 | 183.7 ± 3.12 |
| **HIGH DOSE** | 187.4± 8.14 | 189.6 ± 3.12 | 189.6 ± 2.16 | 190.0± 6.21 | 191.92 ± 2.19 |
| **P value (p)*** | NS | NS | NS | NS | NS |

NS- Not Significant, **(p > 0.01),*(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

**Table 7: Water intake (ml/day) of Wistar albino rats group exposed to MAAMPISIN CHOORANAM**

| DOSE | DAYS | | | | |
|---|---|---|---|---|---|
| | 1 | 6 | 14 | 21 | 28 |
| **CONTROL** | 51.5 ± 7.15 | 50.0 ± 8.23 | 58.5± 6.63 | 49.12±7.19 | 51.5±3.96 |
| **LOW DOSE** | 38.5±3.41 | 39.4±3.62 | 39.27±4.12 | 38.2±3.29 | 39.9±3.13 |
| **MID DOSE** | 36.7±4.13 | 36.3±2.21 | 37.1±4.13 | 38.4±6.31 | 38.4±3.34 |
| **HIGH DOSE** | 32.1±1.32 | 33.2±4.13 | 34.7±3.13 | 32.2±1.73 | 30.4±2.65 |
| **P value (p)*** | NS | NS | NS | NS | NS |

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

**Table 8:Food intake (gm/day) of Wistar albino rats group exposed to MAAMPISIN CHOORANAM**

| DOSE | DAYS | | | | |
|---|---|---|---|---|---|
| | 1 | 7 | 14 | 21 | 28 |
| **CONTROL** | 29.12 ±5.37 | 28.5±4.22 | 29.5±4.27 | 32.5±3.87 | 33.12±6.32 |
| **LOW DOSE** | 33.7±4.98 | 34.3±1.22 | 33.1±6.18 | 35.4±6.12 | 35.6±2.12 |
| **MID DOSE** | 32.2±4.75 | 33.2±6.80 | 37.2±1.25 | 33.4±2.68 | 32.2±1.44 |
| **HIGH DOSE** | 32.2±2.34 | 32.2±2.64 | 34.6±2.16 | 36.2±3.14 | 37.0±1.62 |
| **P value (p)*** | NS | NS | NS | NS | NS |

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test.

**Table 9: Haematological parameters of Wistar albino rats group exposed to MAAMPISIN CHOORANAM**

| Category | Control | Low dose | Mid dose | High dose | P value (p)* |
|---|---|---|---|---|---|
| **Haemoglobin( g/dl)** | 14.8±1.88 | 13.1±3.16 | 13.64±3.66 | 14.28±0.96 | N.S |
| **Total WBC (×$10^3$ l)** | 10.91±2.59 | 10.25±6.73 | 11.28±2.31 | 11.40±6.14 | N.S |
| **Neutrophils( %)** | 32.65±1.06 | 32.13±4.14 | 33.11±1.46 | 34.40±3.20 | N.S |
| **lymphocyte (%)** | 69.34±2.48 | 70.16±6.12 | 71.58±4.66 | 74.13±4.16 | N.S |
| **Monocyte (%)** | 0.78±0.17 | 0.76±0.04 | 0.80±0.13 | 0.83±0.36 | N.S |
| **Eosinohil(%)** | 0.64±0.09 | 0.64±0.16 | 0.75±0.43 | 0.73±0.14 | N.S |
| **Platelets cells$10^3$/µl** | 687.17±8.76 | 722.71± 2.16 | 705.18± 2.0 | 735.16± 3.14 | N.S |
| **Total RBC $10^6$/µl** | 7.99±0.12 | 6.82±1.37 | 7.12±1.89 | 7.18±7.72 | N.S |
| **PCV%** | 37.79±0.6 | 41.35±8.13 | 42.18±1.68 | 43.82±2.54 | N.S |
| **MCHC g/dL** | 33.6±2.23 | 32.19±5.29 | 33.18±4.22 | 32.93±1.24 | N.S |
| **5MCV fL(µ$m^3$)** | 49.17±3.64 | 48.29±1.22 | 50.18±1.24 | 50.94±1.44 | N.S |

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

**Table 10 :Biochemical Parameters of Wistar albino rats group exposed to MAAMPISIN CHOORANAM**

| BIOCHEMICAL PARAMETERS | CONTROL | LOW DOSE | MID DOSE | HIGH DOSE | P Value (p)* |
|---|---|---|---|---|---|
| **GLUCOSE (R) (mg/dl)** | 76.45±13.4 | 76.16±2.34 | 75.26±2.20 | 77.42±2.64 | N.S |
| **T.CHOLOSTEROL( mg/dl)** | 115.26±1.83 | 109.45±4.13 | 118.42±4.78 | 123.22±3.73 | N.S |
| **TRIGLY(mg/dl)** | 46.35±1.48 | 44.22±1.48 | 48.58±1.30 | 47.66±3.33 | N.S |
| **LDL** | 72.81±2.13 | 76.24±8.14 | 74.8±2.14 | 70.64±4.32 | NS |
| **VLDL** | 15.2±2.44 | 14.42±4.64 | 14.04±1.64 | 13.94± 1.46 | NS |
| **HDL** | 26.66±6.88 | 23.86±6.24 | 26.10±2.66 | 30.68±1.12 | NS |
| Ratio 1(T.CHO/HDL) | 4.42±2.44 | 4.46±3.14 | 4.64±2.14 | 4.18 ± 2.12 | NS |
| Ratio 2(LDL/HDL) | 2.83±4.22 | 2.14 ± 2.22 | 2.28± 2.20 | 2.16±6.22 | NS |
| **Albumin(g/dL)** | 3.63±0.17 | 3.18±0.42 | 3.16±2.62 | 2.94±4.16 | NS |

NS- Not Significant,**($p > 0.01$), * ($p > 0.05$), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

**Table 11: Renal function test of of Wistar albino rats group exposed to MAAMPISIN CHOORANAM**

| PARAMETERS | CONTROL | LOW DOSE | MID DOSE | HIGH DOSE | P Value (p)* |
|---|---|---|---|---|---|
| **UREA (mg/dl)** | 13.35±0.99 | 13.14±0.16 | 12.96±1.98 | 12.28±3.62 | N.S |
| **CREATININE (mg/dl)** | 0.28±0.08 | 0.36±0.06 | 0.52±0.04 | 0.66±0.02 | N.S |
| **BUN (mg/dL)** | 15.02±0.10 | 14.28±1.92 | 14.09±1.34 | 14.02±4.32 | NS |
| **URIC ACID (mg/dl)** | 5.17±0.35 | 5.01±1.03 | 5.12±3.15 | 4.58±1.33 | NS |

NS- Not Significant, **(p > 0.01), * (p >0.05) , n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

**Table 12: Liver Function Test of Wistar albino rats group exposed to MAAMPISIN CHOORANAM**

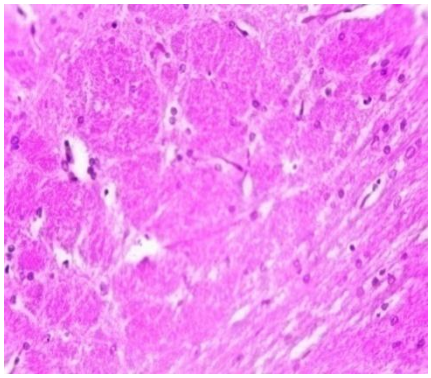
| PARAMETERS | CONTROL | LOW DOSE | MID DOSE | HIGH DOSE | P Value (p)* |
|---|---|---|---|---|---|
| **T BILIRUBIN(mg/dl).** | 0.48±0.07 | 0.40±1.26 | 0.41±3.28 | 0.39±1.25 | N.S |
| **SGOT/AST(U/L)** | 79.95±1.39 | 76.15±1.31 | 77.31±3.03 | 79.25±4.03 | N.S |
| **SGPT/ALT(U/L)** | 31.23±1.28 | 32.91±3.59 | 36.24±7.48 | 34.12±1.68 | N.S |
| **ALP(U/L)** | 143.25±8.70 | 146.12±1.37 | 143.16±4.17 | 145.33±1.65 | NS |
| **T.PROTEIN(g/dL)** | 5.32±0.38 | 5. 22±1.14 | 6.01±3.23 | 6.93±1.46 | N.S |

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

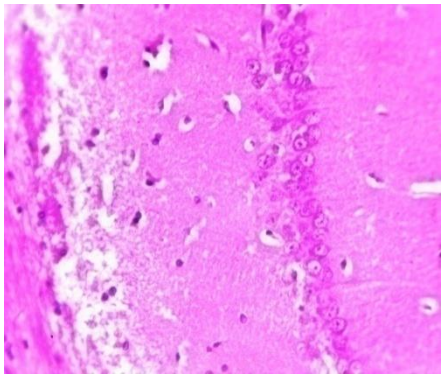
## HISTOPATHOLOGY OF VITAL ORGANS

**Low dose** **High dose**

**BRAIN**

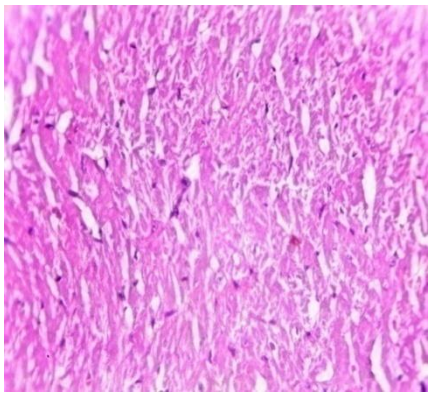


Cerebellum – Normal

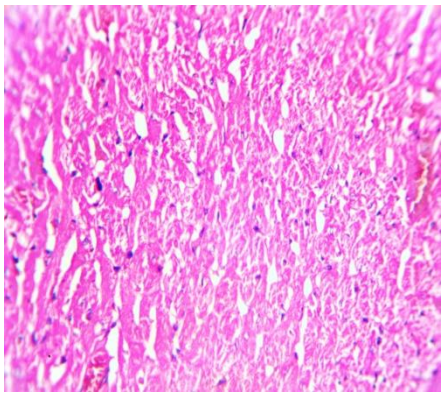


Cerebellum – Mild gliosis

**HEART**

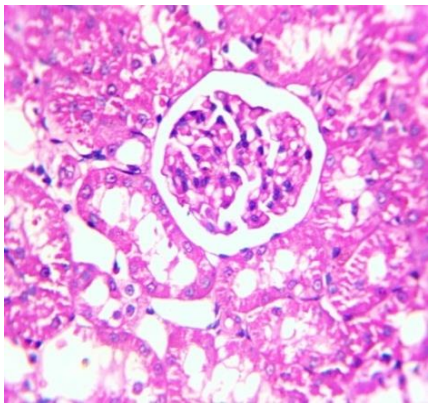


Normal Cardiomyocytes

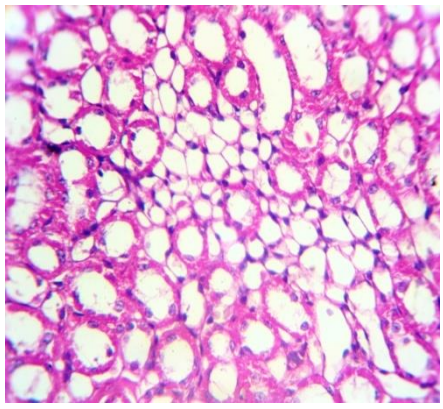


Normal Cardiomyocytes

**KIDNEY**

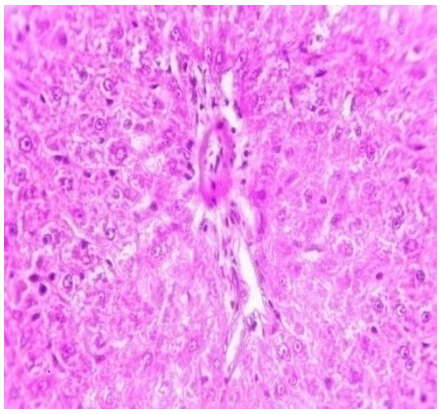


Cortex – Normocellular glomeruli

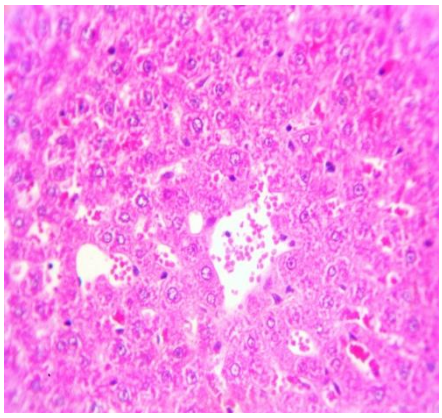


Cortex – Normocellular glomeruli

LIVER

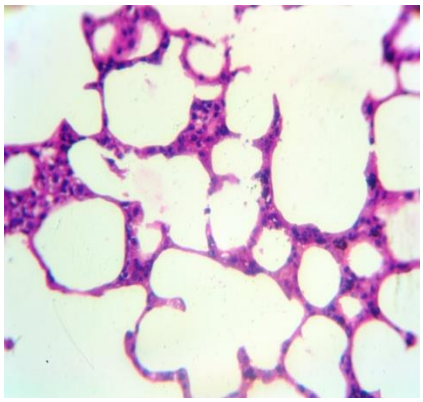


Normal

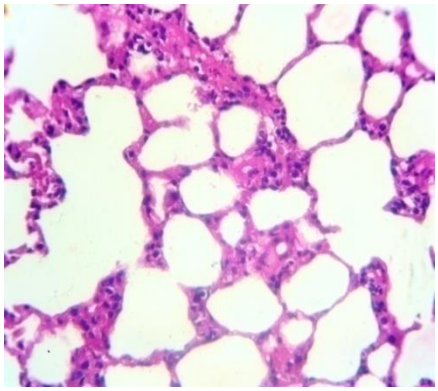


Periportal zone – Normal

LUNG



Normal



Normal

## HISTOPATHOLOGY REPORT

**BRAIN**

Arrangement of the neurons appears intact with no signs of degeneration was observed in sample.

**HEART**

Myocardial fiber mass appears denser with no signs of degeneration or fibrosis were observed in samples.

**LIVER**

Appearance of portal triad was normal with no signs of inflammatory cell infiltration. Liver parenchyma appears normal. No evidence of necrosis were observed in samples.

**KIDNEY**

Appearance of proximal and distal convolutes tubules was normal with no evidence of atrophy.

**LUNG**

Microscopic examination of lung revealed normal alveoli and alveolar sac with no signs of infiltration.

# AN EVALUATION OF THE SIDDHA DRUG MAAMPISIN CHOORANAM FOR ITS STYPTIC ACTIVITY IN WISTER ALBINO RATS

## ANIMAL PROCUREMENT AND MAINTENANCE

Wistar Albino rats of either sex, weighing 150 g to 200 g were purchased from Kings Institute of Preventive medicine Animal House, Chennai, India. Animal ethical guidelines of CPCSEA, Ministry of Animal Husbandry and Welfare, Govt. of India were strictly followed for the care and maintenance of procured animals. The animals were fed on standard rodent pellet and RO water was provided *ad libitum.* The animals were kept for overnight fasting before experimentation.

## DRUG PROFILE

Adrenochrome is a by- product of oxidized adrenaline. Its chemical name is 3-hydroxy-1-methyl-5, 6-indoline-dione. Adrenochrome can refer to two things: a metabolite of endogenous epinephrine or a product of metabolized pharmaceutical epinephrine. This drug is controversial because there are debates as to what class this drug belongs to. Adrenochrome is believed to have psychoactive and hallucinogenic effects. This means that it is believed to change the user's behavior, perception, mood and consciousness and also cause the person to hallucinate. It is believed that adrenochrome may produce effects similar to, but milder than LSD and psilocybin.

## PROCEDURE

Animals were randomized into four groups of six animals each.

1. Group I received vehicle,
2. Group II received test drug 100mg
3. Group III received test drug 200mg
4. Group IV served as standard. (Tranexamic acid-TA)

The animals were administered the test drug orally and the blood sample were collected periodically for evaluation.

**CLOTTING TIME (CT)**

The tail of the animal is warmed for 1 min in water at 40°C, dried and cut at the tip with a razor blade. A 25 µl sample of capillary blood was collected into a microhematocrit glass capillary. The chronometer was started when the blood is first made contact with the glass capillary tube. The blood left to flow by gravity between the two marks of the tube, 45 mm apart, by tilting the capillary tube alternately to +60° and -60° angles with respect to the horizontal plane until blood ceased to flow (reaction end point).

**BLEEDING TIME (BT)**

The tail of the rat is warmed for 1min in water at 40°C and then dried. A small cut was made in the middle of the tail with a scalpel. Bleeding time started and noted when the first drop touched the circular filter paper and checked at 30 s intervals until bleeding stops.

**PROTHROMBIN TIME (PT)**

0.1 ml of plasma mixed with 0.2 ml of PT reagent (calcium thromboplastin) maintain $37^{o}$C, and observe the animals until formation of the fibrin clot. The time should be noted.

**ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)**

0.1 ml of plasma with 0.1mi of APTT reagent (cephalin-karolin suspension) incubated $37^{o}$C for 5 minutes and then adds 0.1ml of 0.025ml cacl2 solution, until formation of the fibrin clot visually detected. The time should be noted.

**FIBRINOGEN TIME**

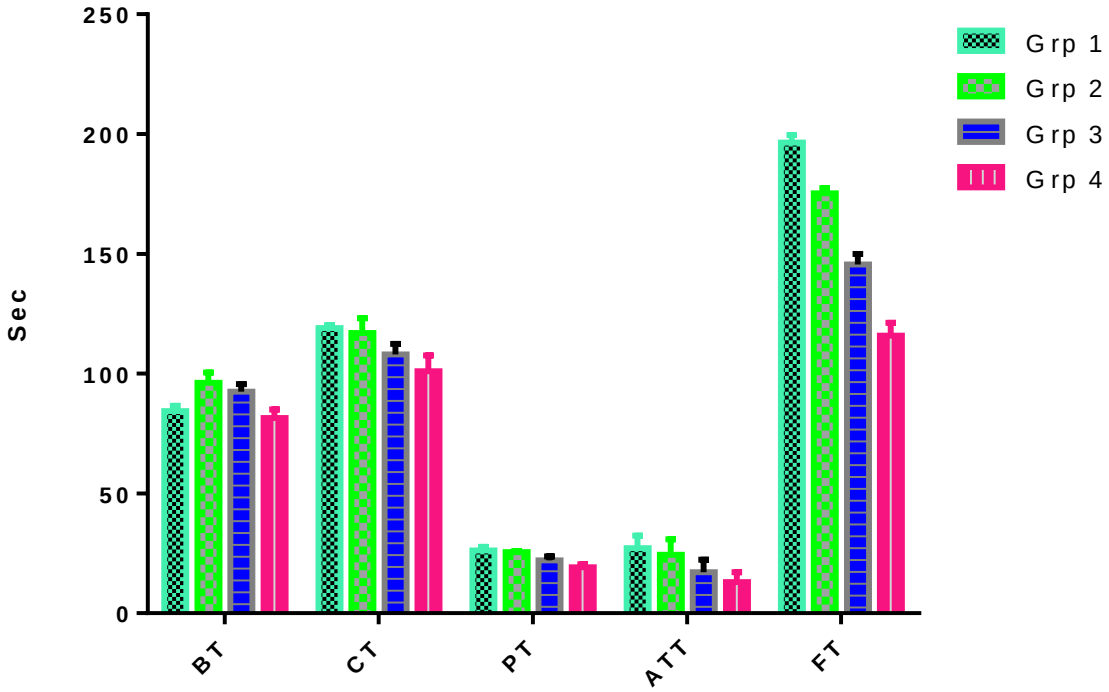
0.25ml of animal blood plasma add 0.05 ml of saline, and incubated $37^{o}$C. After 30sec add 0.1ml of streptokinase solution, wait for 30sec, then add 0.1ml of bovine thrombin added. Start the stopwatch note at which time the fibrinogen clot formed.

**METHOD:**

After, one hour of treatment to the above respective groups, the following parameters such as BT, CT, Prothrombin time, Activated partial Thromboplastin time, Thrombin time and Fibrinogen were screened.

**RESULTS AND DISCUSSION:**

**BLOOD STYPTIC PARAMETERS**



| S. no | Groups | Bleeding time (sec) | Clotting time (sec) | Prothrombin time | Activated Thromboplastin time | Fibrinogen time |
|---|---|---|---|---|---|---|
| 1 | Control | 84.32±2.22 | 119.4±1.24 | 26.26±1.44 | 27.12±5.22 | 196.4±3.22 |
| 2 | Low dose | 96.21±4.21 | 117.2±6.21 | 25.54±0.43 | 24.42±6.42 | 175.2±2.20 |
| 3 | High dose | 92.52±3.11 | 108.6±4.44 | 22.11±1.64 | 17.12±5.22 | 145.6±4.32 |
| 4 | Standard | 81.42±3.64 | 101.7±6.62 | 19.2±1.22 | 13.06±4.11 | 115.8±5.42 |

Values are expressed as mean ± S.D followed by Dunnett's Test. *P < 0.05, **P < 0.01, ***P<0.001 compared.

Haemorrhage is responsible for 50% deaths occurring within 24 hours of traumatic injury. Haemorrhage is also a leading cause of death associated with blood transfusion. There is a need for the improvement of current treatments of bleeding associated with surgery, trauma or other tissue damages. An ideal styptic with fewer side effects and cost effective is the need of the hour. The results of the present investigation show that a significant reduction in the bleeding time, clotting time, prothrombin time and fibrinogen. These were reduced in a dose dependent manner.

**CONCLUSION**

By the observed results, the values of trial drug Maampisin Chooranam treated animals were compared with the positive control drug Adrenochrome 10 µg/animal/i.p, single dose. The results (mean value) are assured as a good styptic activity response of trial drug.

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E-mail : mail@tnmgrmu.ac.in Fax : 91-44-22353698

## PHYSIOCHEMICAL ANALYSIS OF MAAMPSIN CHOORANAM

1. **Loss On Drying:**

An accurately weighed 2g of ***Maampsin Chooranam*** formulation was taken in a tarred glass bottle. The crude drug was heated at 105$^0$C for 6 hours in an oven till a constant weight. The Percentage moisture content of the sample was calculated with reference to the shade dried material.

2. **Determination of total ash:**

Weighed accurately 2g of ***Maampsin Chooranam*** formulation was added in crucible at a temperature 600$^0$C in a muffle furnace till carbon free ash was obtained. It was calculated with reference to the air dried drug.

3. **Determination of acid insoluble ash:**

Ash above obtained, was boiled for 5min with 25ml of 1M Hydrochloric acid and filtered using an ash less filter paper. Insoluble matter retained on filter paper was washed with hot water and filter paper was burnt to a constant weight in a muffle furnace. The percentage of acid insoluble as was calculated with reference to the air dried drug.

4. **Determination of water soluble ash:**

Total ash 1g was boiled for 5min with 25ml water and insoluble matter collected on an ash less filter paper was washed with hot water and ignited for 15 min at a temperature not exceeding 450$^0$C in a muffle furnace. The amount of soluble ash is determined by drying the filtrate.

5. **Determination of water soluble Extractive:**

5gm of air dried drug, coarsely powered ***Maampsin Chooranam*** was macerated with 100ml of distilled water in a closed flask for twenty-four hours, shaking frequently. The Solution was filtered and 25 ml of filtrated was evaporated in a tarred flat bottom shallow dish, further dried at 100$^0$ C and weighted. The percentage of water soluble extractive was calculated with reference to the air dried drugs.

**6. Determination of alcohol soluble extractive:**

2.5gm. of air dried drugs, coarsely powdered ***Maampsin Chooranam*** was macerated with 50 ml. alcohol in closed flask for 24 hrs. With frequent shaking, it was filtered rapidly taking precaution against loss of alcohol. 10ml of filtrate was then evaporated in a tarred flat bottom shallow dish, dried at $100^0$C and weighted. The percentage of alcohol soluble extractive was calculated with reference to air dried drug.

| S.no | Parameters | Percentage |
|---|---|---|
| 1 | Loss on drying | 6.67% |
| 2 | Total ash value | 3.26% |
| 3 | Acid insoluble ash | Less than 1% |
| 4 | Water soluble ash | 1.92% |
| 5 | Water soluble extraction | 36.65% |
| 6 | Alcohol soluble extraction | 21.72% |

The above stated physiochemical properties of the given sample certified to be present.

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## PRELIMINARY PHYTOCHEMICAL SCREENING - MAAMPISIN CHOORANAM

The preliminary phytochemical screening test was carried out for each extracts of ***Maampisin Chooranam*** as per the standard procedure.

**1. Detection of alkaloids:**

Extracts were dissolved individually in dilute Hydrochloric acid and filtered.

**a) Mayer's Test:** Filtrates were treated with Mayer's reagent (Potassium Mercuric Iodide). Formation of a yellow colored precipitate indicates the presence of alkaloids.

**b) Wagner's Test:** Filtrates were treated with Wagner's reagent (Iodine in Potassium Iodide). Formation of brown/reddish precipitate indicates the presence of alkaloids.

**c) Dragendroff's Test:** Filtrates were treated with Dragendroff's reagent (solution of Potassium Bismuth Iodide). Formation of red precipitate indicates the presence of alkaloids.

**d) Hager's Test:** Filtrates were treated with Hager's reagent (saturated picric acid solution). Presence of alkaloids confirmed by the formation of yellow colored precipitate.

**2. Detection of carbohydrates:**

Extracts were dissolved individually in 5 ml distilled water and filtered. The filtrates were used to test for the presence of carbohydrates.

**a) Molisch's Test**:

To 2 ml of plant sample extract, two drops of alcoholic solution of α- naphthol are added. The mixture is shaken well and few drops of concentrated sulphuric acid is added slowly along the sides of test tube. A violet ring indicates the presence of carbohydrates.

**b) Benedict's Test:**

Filtrates were treated with Benedict's reagent and heated gently. Orange red precipitate indicates the presence of reducing sugars.

**3. Detection of glycosides:**

Extracts were hydrolyzed with dil. HCl, and then subjected to test for glycosides.

**a) Modified Borntrager's Test:** Extracts were treated with Ferric Chloride solution and immersed in boiling water for about 5 minutes. The mixture was cooled and extracted with equal volumes of benzene. The benzene layer was separated and treated with ammonia solution. Formation of rose-pink color in the ammonical layer indicates the presence of anthranol glycosides.

**b) Cardiac glycoside (Keller-Killiani test):** Extract was shaken with distilled water (5 mL). To this, glacial acetic acid (2 mL) containing a few drops of ferric chloride was added, followed byH2SO4 (1 mL) along the side of the test tube. The formation of brown ring at the interface gives positive indication for cardiac glycoside and a violet ring may appear below the brown ring

**4. Detection of saponins**

**a) Froth Test:** Extracts were diluted with distilled water to 20ml and this was shaken in a graduated cylinder for 15 minutes. Formation of 1 cm layer of foam indicates the presence of saponins.

**b) Foam Test:** 0.5 gm of extract was shaken with 2 ml of water. If foam produced persists for ten minutes it indicates the presence of saponins.

**5. Detection of phytosterols**

**a) Salkowski's Test:** Extracts were treated with chloroform and filtered. The filtrates were treated with few drops of Conc. Sulphuric acid, shaken and allowed to stand. Appearance of golden yellow color indicates the presence of triterpenes.

**6. Detection of phenols Ferric Chloride Test:**

Extracts were treated with 3-4 drops of ferric chloride solution. Formation of bluish black color indicates the presence of phenols.

**7. Detection of tannins Gelatin Test:**

The extract is dissolved in 5 ml of distilled water and 2 ml of 1% solution of Gelatin containing 10% NaCl is added to it. White precipitate indicates the presence of phenolic compounds.

**8. Detection of Flavonoids**

**a) Alkaline Reagent Test:** Extracts were treated with few drops of sodium hydroxide solution. Formation of intense yellow color, which becomes colorless on addition of dilute acid, indicates the presence of flavonoids.

**b) Lead acetate Test:** Extracts were treated with few drops of lead acetate solution. Formation of yellow color precipitate indicates the presence of flavonoids.

**9. Detection of proteins and aminoacids**

**a) Xanthoproteic Test:** The extracts were treated with few drops of conc. Nitric acid. Formation of yellow color indicates the presence of proteins.

**b) Ninhydrin Test**: To the extract, 0.25% w/v ninhydrin reagent was added and boiled for few minutes. Formation of blue color indicates the presence of amino acid.

**10. Detection of diterpenes Copper Acetate Test**:

Extracts were dissolved in water and treated with 3-4 drops of copper acetate solution. Formation of emerald green color indicates the presence of diterpenes

**11. Gum and Mucilage:**

To 1ml of extract add 2.5ml of absolute alcohol and stirring constantly. Then the precipitate was dried in air and examine for its swelling properties. Swelling was observed that will indicate presence of gum and mucilage.

**12. Test for Fixed oils and Fats**

**a. Spot test :** A small quantity of extract is pressed between two filter papers. Oil stain on the paper indicates the presence of fixed oils.

**13. Test for Quinones**

Extract was treated with sodium hydroxide blue or red precipitate indicates the presence of Quinones.

The Preliminary phytochemical studies of aqueous extract of ***Maampisin Chooranam*** were done using standard procedures. The results were presented in tables. The present study reveals that the bioactive compounds were present in all the extracts of ***Maampisin Chooranam***.

| S.no | Phytochemicals | Test Name | H2O Extract |
|---|---|---|---|
| 1. | Alkaloids | Mayer's Test | -ve |
| | | Wagner's Test | -ve |
| | | Dragendroff's Test | -ve |
| | | Hager's Test | -ve |
| 2. | Carbohydrates | Molisch's Test: | +ve |

| | | | |
|---|---|---|---|
| | | Benedict's Test | +ve |
| 3. | Glycoside | Modified Borntrager's Test | -ve |
| | | Keller Killiani | -ve |
| 4. | Saponin | Froth Test | +ve |
| | | Foam Test | -ve |
| 5. | Phytosterol | Salkowski's Test | -ve |
| 6. | Phenols | Ferric Chloride Test | +ve |
| 7. | Tannins | Gelatin Test | -ve |
| 8. | Flavonoids | Alkaline Reagent Test | +ve |
| | | Lead acetate Test | +ve |
| 9. | Proteins and amino acids | Xanthoproteic Test | +ve |
| 10. | Diterpenes | Copper Acetate Test | +ve |
| 11. | Gum & Mucilage | Extract + Alcohol | +ve |
| 12. | Fat & Fixed Oil | Spot Test | -ve |
| 13. | Quinones | NAOH + Extract | +ve |

**+ve/-ve present or absent if component tested**

The above stated phytochemical properties of the given sample certified to be present.

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# BIO-CHEMICAL ANALYSIS OF TRIAL MEDICINE

**Preparation of Sodium Carbonate extract:**

2 gm of the sample drug is mixed 5 gm of Sodium carbonate and taken in a 100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called sodium carbonate extract.

| S.No | EXPERIMENT | OBSERVATION | INFERENCE |
|---|---|---|---|
| I | **TEST FOR ACID RADICALS** | | |
| 1a | **Test for Sulphate**<br>2 ml of the above prepared extract is taken in a test tube. To this add 2ml of 4% Ammonium oxalate solution. | Absence of White Precipitate | Absent |
| b | 2ml of extract is added with 2ml of dilute hydrochloric acid until the effervescence ceases off. Then 2ml barium chloride solution is added. | Absence of White Precipitate | Absent |
| 2 | **Test for Chloride:**<br>2ml of extract is added with dilute nitric acid till the effervescence ceases. Then 2ml of silver nitrate solution is added. | Absence of white precipitate obtained | Absent |
| 3 | **Test for Phosphate**<br>2ml of the extract is treated with 2 ml of Ammonium molybdate solution and 2ml of concentrated nitric acid. | Yellow precipitate obtained | Present |

| | | | |
|---|---|---|---|
| 4 | **Test for Carbonate:**<br>2ml of the extract is treated with 2ml of magnesium sulphate solution. | Absence of white precipitate | Absent |
| 5 | **Test for Sulphide:**<br>1 gm of the substance is treated with 2ml of concentrated Hydrochloric acid | Rotten egg smelling | Absent |
| 6 | **Test for Nitrate:**<br>1gm of the substance is heated with copper turnings and concentrated sulphuric acid and viewed the test tube vertically down. | Absence of reddish brown gas. | Absent |
| 7a | **Test for Fluoride and oxalate**<br>2ml of the extract is added with 2ml of dilute acetic acid and 2ml of calcium chloride solution and heated. | White precipitate | Absent |
| b | 5 drops of clear solution is added with 2ml of dilute sulphuric acid and slightly warmed to this, 1 ml of dilute potassium permanganate solution is added. | KMNO4 solution Discolourisation obtained | Absent |
| 8 | **Test for Nitrite**<br>3 drops of the extract is placed on a filter paper. On that, 2 drops a Acetic Acid and 2 drops of Benzidine solution is placed. | Absence of yellowish red colour | Absent |
| 9 | **Test for Borate** | Absence of Green | Absent |

| | | | |
|---|---|---|---|
| | 2 pinches of the substance is made into paste by using Sulphuric acid and Alcohol (95%) and introduced into the blue flame. | tinged flame | |
| II | **TEST FOR BASIC RADICALS** | | |
| 10 | **Test for lead**<br>2 ml of the extract is added with 2 ml of Potassium iodide solution. | Absence of Yellow precipitate | Absent |
| 11a | **Test for Copper**<br>One pinch of substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the non luminous part of the flame. | Absence of Bluish green coloured flame. | Absent |
| b | 2ml of the extract is added with excess of Ammonia solution | Absence of deep blue | Absent |
| 12 | **Test for Aluminium**<br>To the 2 ml of extract. Sodium Hydroxide solution is added in drops to excess. | Absence of White Precipitate. | Absent |
| 13a | **Test for Iron**<br>To the 2 ml of extract, 2 ml of Ammonium Thiocyanate Solution is added. | Blood red colour | Present |
| b | To the 2 ml of extract, 2 ml of Ammonium Thiocyanate solution and 2 ml of concentrated $HNO_3$ is added. | Blood red colour obtained | Present |
| 14 | **Test for Zinc** | Absence of White | Absent |

| | | | |
|---|---|---|---|
| | To the 2 ml of extract Sodium Hydroxide solution is added in drops to excess. | precipitate. | |
| 15 | **Test for Calcium**<br>2 ml of the extract is added with 2 ml of 4% Ammonium Oxalate solution. | Absence of White precipitate. | Absent |
| 16 | **Test for Magnesium**<br>2ml of extract, Sodium Hydroxide solution is added in drops to excess. | Absence of White precipitate. | Absent |
| 17 | **Test for Ammonium**<br>2 ml of extract few ml of Nessler's Reagent and excess of Sodium Hydroxide solution are added. | Absence of Reddish brown precipitate | Absent |
| 18 | **Test for Potassium**<br>A pinch of substance is treated with 2 ml of Sodium Nitrite solution and then treated with 2 ml of Cobal Nitrate in 30% glacial Acetic acid. | Absence of Yellow precipitate | Absent |
| 19 | **Test for Sodium**<br>2 pinches of the substance is made into paste by using Hydrochloric acid and introduced into the blue flame | Absence of Yellow colour flame | Absent |
| 20 | **Test for Mercury**<br>2 ml of the extract is treated with 2 ml of Sodium Hydroxide solution. | Absence of yellow precipitate | Absent |
| 21 | **Test for Arsenic**<br>2 ml of extract is treated with 2 | Absence of Yellow precipitate | Absent |

| | | | |
|---|---|---|---|
| | ml of silver Nitrate solution | | |
| 22 | **Test for Starch**<br>2ml of extract is treated with weak iodine solution | Absence of<br>Blue colour | Absent |
| 23 | **Test of reducing Sugar**<br>5ml of Benedicts qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2 minutes. The colour changes are noted. | Green colour | Present |
| 24 | **Test of the alkaliods**<br>2ml of the extract is treated with 2ml of potassium lodide solution. | Absence of<br>Red colour | Absent |
| 25 | **Test of the proteins**<br>2ml of the extract is treated with 2ml of 5% NaOH ,mix well and add 2 drops of copper sulphate solution. | Absence of<br>Violet colour | Absent |

**RESULTS:**

The given sample (Maampisin Chooranam) contains

i) Phosphate

ii) Iron

iii) Reducing sugar.

## GOVERNMENT SIDDHA MEDICAL COLLEGE
**Arumbakkam, Chennai-106**

**Communication Of The Decision Of Institutional Ethics Committee (IEC)**

**IEC No: GSMC-CH-ME-5/003/2016**

| |
|---|
| **Protocol title:**<br>AN OPEN NON-RANDOMIZED CLINICAL TRIAL OF MAAMPISIN CHOORANAM IN PITHA PERUMBADU (MENORRHAGIA). |
| **Principal Investigator:** Dr. A. DHIVYA BHARATHI |
| **Name & Address of Institution:**<br>Government Siddha Medical College,<br>Arumbakkam, Chennai-106 |
| ☑ New Review ☐ Revised Review ☐ Expedited Review |
| Date of review (DD/MM/YY): 05-04-2016<br>Date of Previous Review, If Revised Application: |
| Decision of the IEC<br>☑ Recommended ☐ Recommended with suggestions<br>☐ Revision ☐ Rejected |
| Suggestions / Reasons / Remarks:<br>1) Sample size should be increased to 30.<br>2) Dosage changes from 1g to 2g.<br>3) Endometrial cancer should be added in Exclusion Criteria. |
| Recommended for a period of 1 year<br>from date of completion of preclinical studies : |

**Please Note:**

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

5/4/16.

**Dr.P.Jeyaprakashnarayanan, M.D(s)**
**Chairman**

**Dr.K.Kanakavalli, M.D(s)**
**Member Secretary**

# INSTITUTIONAL ETHICS COMMITTEE

Date : 05.04.2016
Sub : IEC review of research proposals.
Ref : Your letter dated

| MEMBERS | PARTICIPATION | SIGNATURE |
|---|---|---|
| Dr.P.JEYAPRAKASH NARAYANAN, M.D(S)., Chairman | ✓ | |
| Dr.K.KANAKAVALLI, M.D(S)., Member secretary | ✓ | |
| Dr.P.SATHYA RAJESWARAN, M.D(S)., Clinician – Siddha | ✓ | |
| Dr.N.KABILAN, M.D(S)., Clinician – Siddha | ✓ | |
| Dr.R.VASUDEVAN, M.D(S)., PG.DIP (Clinical research), Msc (Medical sociology) Sociologist | ✓ | |
| Dr.L.MUKUNTHAN, M.B.B.S., DNB (Medicine)., Modern Medicine Specialist | ✓ | |
| Dr. JOSEPH MARIYA ADAIKKALAM,M.D(S)., Msc epidemiology., Social scientist | ✓ | |
| Dr.G.AADINATH REDDY, M.Pharm, Ph,D., Biomedical scientist | ✓ | 05/04/16 |
| Mr.B.PADMANABHA PILLAI Philosopher | ✓ | |
| Mrs. PREETHA SARAVANAN Public person | ✓ | 05/04/16 |

Dr. P. Jeyaprakashnarayanan, M.D(s)
Chairman

Dr.K. Kanakavalli, M.D(s)
Member secretary

## BIO STATISTICAL ANALYSIS

**Treatment for Pitha Perumbadu:**

The most popular non parametric statistical tool, namely, McNemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

**NO. OF PADS**

Software: spss17 version

Variables: Number of Pads– before treatment, after treatment

Number of cases: 30

| S. NO | OP. NO | PATIENT'S AGE | NUMBER OF PADS FOR A CYCLE | |
|---|---|---|---|---|
| | | | BEFORE TREATMENT | AFTER TREATMENT |
| 1 | 4819 | 38 | 21 | 9 |
| 2 | 684 | 28 | 32 | 20 |
| 3 | 8610 | 48 | 26 | 21 |
| 4 | 891 | 37 | 22 | 8 |
| 5 | 124 | 23 | 30 | 10 |
| 6 | 2768 | 45 | 20 | 9 |
| 7 | 8802 | 17 | 39 | 21 |
| 8 | 5812 | 28 | 21 | 13 |
| 9 | 3196 | 22 | 28 | 16 |
| 10 | 1004 | 30 | 25 | 14 |
| 11 | 3663 | 44 | 16 | 8 |
| 12 | 3797 | 37 | 22 | 10 |
| 13 | 8539 | 42 | 23 | 10 |
| 14 | 3842 | 37 | 22 | 9 |
| 15 | 825 | 45 | 27 | 20 |
| 16 | 6713 | 23 | 17 | 10 |
| 17 | 6942 | 44 | 29 | 9 |
| 18 | 2756 | 46 | 25 | 14 |
| 19 | 5585 | 38 | 21 | 9 |
| 20 | 7293 | 35 | 19 | 11 |
| 21 | 5007 | 47 | 22 | 18 |
| 22 | 728 | 41 | 23 | 13 |
| 23 | 4927 | 33 | 26 | 16 |
| 24 | 6610 | 36 | 20 | 10 |
| 25 | 8665 | 37 | 25 | 14 |
| 26 | 8404 | 42 | 26 | 13 |
| 27 | 5582 | 42 | 21 | 11 |
| 28 | 320 | 41 | 30 | 26 |
| 29 | 7497 | 47 | 22 | 10 |
| 30 | 1397 | 42 | 26 | 17 |

**Paired Samples Statistics**

| | Mean | N | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|
| PADS_BT | 20.1667 | 30 | 4.25144 | .77620 |
| PADS_AT | 11.6667 | 30 | 3.41733 | .62392 |

**Paired Samples Test**

| | Paired Differences | | | | | t | df | Sig. (2-tailed) |
|---|---|---|---|---|---|---|---|---|
| | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference | | | | |
| | | | | Lower | Upper | | | |
| PADS_BT - PADS_AT | 8.50000 | 3.94575 | .72039 | 7.02663 | 9.97337 | 11.799 | 29 | .000 |

**Inference:**

Since the P value is highly significant (<0.00), The hypothesis is not accepted. So the treatment was significantly reducing the number of pads used by the patients for the treatment of Pitha Perumbadu.

**HAEMOGLOBIN LEVEL:**

**Software:** spss17 version

**Variables:** Hb level (gm/dl)– before treatment, after treatment

**Number of cases: 30**

| S. NO | OP. NO | PATIENT'S AGE | HEMOGLOBIN LEVEL IN GMS/100ML OF BLOOD | |
|---|---|---|---|---|
| | | | BEFORE TREATMENT | AFTER TREATMENT |
| 1 | 4819 | 38 | 8.1 | 10.3 |
| 2 | 684 | 28 | 7.9 | 9.1 |
| 3 | 8610 | 48 | 9.0 | 10.4 |
| 4 | 891 | 37 | 11.5 | 12.0 |
| 5 | 124 | 23 | 6.3 | 7.7 |
| 6 | 2768 | 45 | 9.1 | 10.0 |
| 7 | 8802 | 17 | 9.8 | 11.0 |
| 8 | 5812 | 28 | 7.7 | 9.3 |
| 9 | 3196 | 22 | 8.5 | 10.1 |
| 10 | 1004 | 30 | 6.8 | 7.5 |
| 11 | 3663 | 44 | 8.3 | 9.0 |
| 12 | 3797 | 37 | 7.1 | 8.5 |
| 13 | 8539 | 42 | 10.2 | 11.1 |
| 14 | 3842 | 37 | 9.7 | 10.6 |
| 15 | 825 | 45 | 9.0 | 10.5 |
| 16 | 6713 | 23 | 10 | 12.2 |
| 17 | 6942 | 44 | 10.4 | 12.0 |
| 18 | 2756 | 46 | 8.2 | 10.0 |
| 19 | 5585 | 38 | 9.6 | 11.0 |
| 20 | 7293 | 35 | 10 | 11.8 |
| 21 | 5007 | 47 | 8.0 | 9.5 |
| 22 | 728 | 41 | 9.0 | 10.2 |
| 23 | 4927 | 33 | 11.0 | 11.9 |
| 24 | 6610 | 36 | 11.2 | 12.1 |
| 25 | 8665 | 37 | 8.3 | 10.2 |
| 26 | 8404 | 42 | 9.3 | 11.7 |
| 27 | 5582 | 42 | 10.5 | 12.0 |
| 28 | 320 | 41 | 7.0 | 9.9 |
| 29 | 7497 | 47 | 9.2 | 10.5 |
| 30 | 1397 | 42 | 8.0 | 9.3 |

**Paired Samples Statistics**

| | | Mean | N | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Pair 1 | HB_BT | 8.9567 | 30 | 1.33434 | .24362 |
| | HB_AT | 10.3800 | 30 | 1.28530 | .23466 |

**Paired Samples Test**

| | | Paired Differences | | | | | t | df | Sig. (2-tailed) |
|---|---|---|---|---|---|---|---|---|---|
| | | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference | | | | |
| | | | | | Lower | Upper | | | |
| Pair 1 | HB_BT - HB_AT | -1.42333 | .53863 | .09834 | -1.62446 | -1.22220 | -14.474 | 29 | .000 |

**Inference:**

Since the P value is highly significant (<0.000), The hypothesis is not accepted. So the treatment was significantly improving the Hb level among the patients for the treatment of Pitha Perumbadu.

**BLEEDING TIME:**

**Software:** spss17 version

**Variables:**bleeding time(min)– before treatment, after treatment

**Number of cases: 30**

| S. NO | OP. NO | AGE | BLEEDING TIME Min'Sec'' | | CLOTTING TIME Min'Sec'' | |
|---|---|---|---|---|---|---|
| | | | BT | AT | BT | AT |
| 1 | 4819 | 38 | 3'09'' | 2'10'' | 5'48'' | 4'25'' |
| 2 | 684 | 28 | 2'40'' | 1'12'' | 5'28'' | 5'10'' |
| 3 | 8610 | 48 | 2'10'' | 2'02'' | 4'22'' | 3'56'' |
| 4 | 891 | 37 | 2'36'' | 1'10'' | 4'52'' | 5'25'' |
| 5 | 124 | 23 | 3'21'' | 2'42'' | 4'46'' | 4'16'' |
| 6 | 2768 | 45 | 2'15'' | 1'59'' | 4'11'' | 3'59'' |
| 7 | 8802 | 17 | 2'28'' | 2'09'' | 5'42'' | 4'30'' |
| 8 | 5812 | 28 | 3'36'' | 2'06'' | 3'24'' | 3'20'' |
| 9 | 3196 | 22 | 2'55'' | 2'02'' | 6'10'' | 5'39'' |
| 10 | 1004 | 30 | 1'48'' | 1'12'' | 5'22'' | 5'10'' |
| 11 | 3663 | 44 | 4'29'' | 3'10'' | 6'44'' | 5'27'' |
| 12 | 3797 | 37 | 2'02'' | 1'58'' | 6'42'' | 6'12'' |
| 13 | 8539 | 42 | 2'54'' | 1'45'' | 4'48'' | 4'20'' |
| 14 | 3842 | 37 | 2'10'' | 2'09'' | 3'48'' | 3'15'' |
| 15 | 825 | 45 | 2'18'' | 1'59'' | 4'49'' | 4'25'' |
| 16 | 6713 | 23 | 2'32'' | 2'06'' | 5'27'' | 5'10'' |
| 17 | 6942 | 44 | 2'51'' | 1'46'' | 4'49'' | 4'20'' |
| 18 | 2756 | 46 | 1'28'' | 1'10'' | 4'14'' | 3'59'' |
| 19 | 5585 | 38 | 3'14'' | 2'58'' | 5'40'' | 4'16'' |
| 20 | 7293 | 35 | 2'11'' | 1'44'' | 5'08'' | 4'30'' |
| 21 | 5007 | 47 | 1'48'' | 1'18'' | 5'22'' | 5'32'' |
| 22 | 728 | 41 | 3'08'' | 2'05'' | 5'47'' | 5'16'' |
| 23 | 4927 | 33 | 3'27'' | 2'44'' | 6'02'' | 6'41'' |
| 24 | 6610 | 36 | 2'42'' | 2'15'' | 5'38'' | 5'51'' |
| 25 | 8665 | 37 | 3'26'' | 2'10'' | 4'21'' | 4'20'' |
| 26 | 8404 | 42 | 1'23'' | 1'06'' | 3'28'' | 3'25'' |
| 27 | 5582 | 42 | 2'10'' | 2'11'' | 5'44'' | 5'15'' |
| 28 | 320 | 41 | 4'42'' | 3'10'' | 5'40'' | 4'59'' |
| 29 | 7497 | 47 | 2'15'' | 1'27'' | 4'35'' | 4'30'' |
| 30 | 1397 | 42 | 3'11 | 2'52'' | 4'18'' | 4'21'' |

**Paired Samples Statistics**

| | | Mean | N | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Pair 1 | BLT_BT | 2.5330 | 30 | .77128 | .14082 |
| | BLT_AT | 1.8690 | 30 | .57659 | .10527 |

**Paired Samples Test**

| | Paired Differences | | | | | t | df | Sig. (2-tailed) |
|---|---|---|---|---|---|---|---|---|
| | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference | | | | |
| | | | | Lower | Upper | | | |
| BLT_BT - BLT_AT | .66400 | .42843 | .07822 | .50402 | .82398 | 8.489 | 29 | .000 |

## 1. CLOTTING TIME

**Paired Samples Statistics**

| | | Mean | N | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| | CLT_AT | 4.8897 | 30 | .85205 | .15556 |
| | CLT_BT | 4.5447 | 30 | .83550 | .15254 |

**Paired Samples Test**

| | | Paired Differences | | | | | t | df | Sig. (2-tailed) |
|---|---|---|---|---|---|---|---|---|---|
| | | Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference | | | | |
| | | | | | Lower | Upper | | | |
| Pair 1 | CLT_AT - CLT_BT | .34500 | .46841 | .08552 | .17009 | .51991 | 4.034 | 29 | .000 |

**Inference:**

Since the P value is significant (<0.000), The hypothesis is not accepted. So the treatment was significantly reducing the bleeding time among the patients for the treatment of Pitha Perumbadu.

**PICTORIAL BLOOD LOSS ASSESSMENT SCORE**

**Software:** spss17 version
**Variables:** PBAC score– before treatment, after treatment
**Number of cases: 30**

| S.NO | OP.NO | BEFORE TREATMENT | AFTER TREATMENT | PROGNOSIS |
|---|---|---|---|---|
| 1 | 4819 | 335 | 95 | Good |
| 2 | 684 | 295 | 145 | Moderate |
| 3 | 8610 | 276 | 180 | Mild |
| 4 | 891 | 340 | 80 | Good |
| 5 | 124 | 350 | 100 | Good |
| 6 | 2768 | 323 | 95 | Good |
| 7 | 8802 | 355 | 185 | Mild |
| 8 | 5812 | 250 | 95 | Good |
| 9 | 3196 | 405 | 125 | Moderate |
| 10 | 1004 | 402 | 100 | Good |
| 11 | 3663 | 211 | 98 | Good |
| 12 | 3797 | 285 | 95 | Good |
| 13 | 8539 | 265 | 100 | Good |
| 14 | 3842 | 308 | 85 | Good |
| 15 | 825 | 295 | 135 | Moderate |
| 16 | 6713 | 213 | 90 | Good |
| 17 | 6942 | 305 | 100 | Good |
| 18 | 2756 | 284 | 100 | Good |
| 19 | 5585 | 295 | 90 | Good |
| 20 | 7293 | 272 | 100 | Good |
| 21 | 5007 | 225 | 130 | Moderate |
| 22 | 728 | 230 | 95 | Good |
| 23 | 4927 | 360 | 140 | Moderate |
| 24 | 6610 | 200 | 95 | Good |
| 25 | 8665 | 230 | 100 | Good |
| 26 | 8404 | 275 | 95 | Good |
| 27 | 5582 | 320 | 90 | Good |
| 28 | 320 | 420 | 300 | Mild |
| 29 | 7497 | 310 | 99 | Good |
| 30 | 1397 | 355 | 145 | Moderate |

**PBAC SCORE BEFORE TREATMENT**

| | | **Frequency** | **percentage** |
|---|---|---|---|
| **Valid** | 1.00 | 16 | 53.3 |
| | 2.00 | 11 | 36.7 |
| | 3.00 | 3 | 10.0 |
| | **Total** | 30 | 100.0 |

1= 200-300 points

2= 301-400 points

3=401-500 points

**PBAC SCORE BEFORE TREATMENT**

| | |
|---|---|
| Mean | 299.7333 |
| Std. Deviation | 58.64030 |
| Minimum score | 200.00 |
| Maximum score | 420.00 |

**AFTER TREATMENT**

**PBAC SCORE AFTER TREATMENT**

| | | **Frequency** | **percentage** |
|---|---|---|---|
| **Valid** | 1.00 | 21 | 70.0 |
| | 2.00 | 6 | 20.0 |
| | 3.00 | 3 | 10.0 |
| | **Total** | 30 | 100.0 |

1= ≤ 100

2 =101 – 150

3 = > 150

**PBAC SCORE AFTER TREATMENT**

| | |
|---|---|
| Mean | 116.0667 |
| Minimum | 80.00 |
| Maximum | 300.00 |

**Inference:**

By using PCAB, in before treatment the mean score was 299.73. The maximum score was 200 and the minimum score was 420. Whereas in the after treatment there was a significant decrease in the scores, the mean score was 116.066, the maximum score was 80 and the minimum score was 300.

**GOVERNMENT SIDDHA MEDICAL COLLEGE**

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

**AN OPEN NON-RANDOMIZED CLINICAL TRIAL OF**

**MAAMPISIN CHOORANAM**

**IN PITHA PERUMBADU (MENORRHAGIA)**

INFORMED CONSENT FORM

*"**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.***

***I consent voluntarily to participate in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care**".*

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant:

In case of illiterate participant

*"**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely**."*

Date:

Signature of a witness Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

Station:

Signature of participant:

Signature of the Guide: Signature of the Investigator:

**அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106**

**அறிஞர் அண்ணா மருத்துவமனை சென்னை**

**பித்த பெரும்பாடு நோய்க்கான சித்த மருந்தின் (மாம்பிசின் சூரணம்)**

**பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்**

***ஒப்புதல் படிவம்***

**ஆய்வாளரால் சான்றளிக்கப்பட்டது**

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

**தேதி:** **கையொப்பம்:**

**இடம்:** **பெயர்:**

**<u>நோயாளியின் ஒப்புதல்</u>**

என்னிடம் இந்த ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும் தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு நோய்க்கான மாம்பிசின் சூரணம் மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

**தேதி:** **கையொப்பம்:**
**இடம்:** **பெயர்:**

**தேதி:** **சாட்சிக்காரர் கையொப்பம்:**

**இடம்:** **பெயர்:**
**உறவுமுறை:**

**துறைத்தலைவர் கையொப்பம் :** **ஆராய்ச்சியாளர் கையொப்பம்:**

**CASE SHEET PROFORMA**

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,**

**CHENNAI-106**

**POST GRADUATE DEPARTMENT BRANCH –I MARUTHUVAM**

**CASE SHEET PROFORMA FOR PITHA PERUMBADU**

| | | | |
|---|---|---|---|
| **OP No / IP No** | **:** | **Nationality** | **:** |
| **Indian** | | | |
| **Ward No** | **:** | **Religion** | **:** |
| **Bed No** | **:** | **D.O.A** | **:** |
| **Name** | **:** | **D.O.D** | **:** |
| **Age** | **:** | | |
| **Sex** | **: Female** | **Diagnosis** | **:** |
| **Occupation** | **:** | | |
| **Income** | **:** | | |
| **Permanent Address** | **:** | | |

**Temporary Address : Govt. Siddha Medical college,**

**Chennai-600106**

**1.Complaints and duration :**

**2. History of present illness :**

**3. History of past illness :**

**4. Personal history :**

**5. Occupational history :**

**6. Menstrual history :**

**a) Regularity of cycle : Regular / Irregular**

**b) Length of cycle (days) :**

**c) Duration of flow (days) :**

**d) Level of flow : Low/ Moderate /Heavy**

**e) Abdominal pain : Nil/ Mild/ Moderate/ Severe**

**f) LMP :**

**g) Number of pads used per cycle :**

**7. Personal Habits : Veg /non-veg / smoker /Alcoholic / Tobacco hewer**

**8. Family History :**

**9.Obstetric History :**

**GENERAL EXAMINATION**

**Patient consciousness :**

**Body Built :**

**Nourishment :**

**Anaemia :**

**Jaundice :**

**Cyanosis :**

**Clubbing :**

**JVP :**

**Tracheal deviation :**

**Pedal oedema :**

**Lymph adenopathy :**

**VITAL SIGNS**

**Heart rate :**

**Pulse rate :**

**Respiratory rate :**

**Blood Pressure :**

**Body Temperature :**

**Weight :**

**Height :**

**SIDDHA ASPECT**

**NILAM**

**Kurinchi :**

**Mullai :**

**Marutham :**

**Neithal :**

**Palai :**

**PARUVAKAALAM**

**Kaar kalam :**

**Koor kalam :**

**Munpani kalam :**

**Pinpani kalam :**

**Elavenil kalam :**

**Muduvenil :**

**YAAKKAI (Udal)**

**Vaatham :**

**Pitham :**

**Kabam :**

**Kalappu :**

**GUNAM**

**Satthuvam :**

**Rajotham :**

**Thamasam :**

**PORI/PULANGAL (SENSORY ORGANS)**

**Mei (Sensation) :**

**Vaai ( Taste) :**

**Kan( Vision) :**

**Mooku ( Smell) :**

**Sevi ( Hearing) :**

**KANMENTHRIYAM/KANNMAVIDAYAM [MOTOR ORGANS]**

**Kai ( Dhaanam) :**

**Kaal ( Kamanam) :**

**Vaai ( Vasanam) :**

**Eruvaai( Visarkkam) :**

**Karuvaai (Aanantham) :**

**UYIR THATHUKKAL**

**VATHAM**

**Praanan :**

**Abanan :**

**Viyanan :**

**Udanan :**

**Samanan :**

**Nagan :**

**Koorman :**

**Kirukaran :**

**Devathathan :**

**Thananjeyan :**

**PITHAM**

**Anar pitham :**

**Ranjaga pitham :**

**Saathaga pitham :**

**Pirasaga pitham :**

**Alosaga pitham :**

**KAPAM**

**Avalambagam :**

**Kilethagam :**

**Pothagam :**

**Tharpagam :**

**Santhigam :**

**UDALTHAATHUKKAL**

**Saaram :**

**Senner :**

**Oon :**

**Kozhuppu :**

**Enbu :**

**Moolai :**

**Suronitham :**

**ENVAGAI THERVUGAL**

**1. Naa :**

**2. Niram :**

**3. Mozhi :**

**4. Vizhi :**

**5. Sparisam :**

**6. Malam :**

**7. Naadi :**

**8. Moothiram :**

**a) Neer Kuri :**

**Niram :**

**Manam :**

**Edai :**

**Nurai :**

**Enjal :**

**b) Nei Kuri :**

**MODERN ASPECT**

**Sytemic Examination**

**Inspection :**

**Palpation :**

**Percussion :**

**Auscultation :**

**Others Systems**

**Cardio Vascular System :**

**Respiratory system :**

**Central nervous system :**

**Genito urinary system :**

**Endocrine system :**

**CLINICAL SIGNS AND SYMPTOMS OF PERUMBADU**

| Symptoms | Before Treatment | After Treatment | | | | |
|---|---|---|---|---|---|---|
| | | I 7 days | II 9 Days | III 12 Days | IV 30 Days | V 48 Days |
| 1.Vaginal Bleeding No of pads | | | | | | |
| 2. Vaginal Bleeding No of days | | | | | | |
| 3.Passing blood clots | | | | | | |
| 4. Abdomen pain | | | | | | |
| 5. Loss of appetite | | | | | | |
| 6. Anaemia | | | | | | |
| 7.Myalgia | | | | | | |
| 8.Tiredness | | | | | | |
| 9. Head ache | | | | | | |
| 10. Giddiness | | | | | | |

**INVESTIGATIONS**

**1. BLOOD INVESTIGATIONS :**

| **BLOOD INVESTIGATIONS** | | **BEFORE TREATMENT** | **AFTER TREATMENT** |
|---|---|---|---|
| **Hb (gms/dl)** | | | |
| **T.RBC(millions cells/cu.mm)** | | | |
| **ESR (mm)** | **½ hr** | | |
| | **1 hr** | | |
| **T.WBC (cells/cu.mm)** | | | |
| **Differntial Count (%)** | **Polymorphs** | | |
| | **Lymphocytes** | | |
| | **Eosinophils** | | |

| **BLOOD INVESTIGATIONS** | **BEFORE TREATMENT** | **AFTER TREATMENT** |
|---|---|---|
| **Bleeding Time** | | |
| **Clotting Time** | | |
| **Blood glucose (mg/dl) (R)** | | |
| **Blood Urea** | | |
| **Serum Cholestrol** | | |

**2. URINE INVESTIGATION**

| **URINE INVESTIGATIONS** | **BEFORE TREATMENT** | **AFTER TREATMENT** |
|---|---|---|
| **Albumin** | | |
| **Sugar** | | |
| **Deposits** | | |

**3. SONOGRAPHY**

**USG Abdomen and Pelvis**

**4. SMEAR STUDY**

**PAP smear**

**CASE SUMMARY**

**DIAGNOSIS : PITHA PERUMBADU**

**TRIAL DRUG : Maampisin Chooranam**

**Dose : 2 gm; Thrice a day after food .**

**Duration of Treatment : 1-15 days for 3 consecutive cycles**

**REPORTS :**

| DATE | WEEKLY REPORTS | MEDICINE |
|---|---|---|
| | | |

| DATE | WEEKLY REPORTS | MEDICINE |
|---|---|---|
| | | |

**ADVICE :**

**DO'S :**

Take balanced and healthy food.

Take rest in comfort bed

Use sanitary pads.

**DON'TS :**

Don't travel

Don't do heavy work

**PROGNOSIS AT THE END OF THE TREATMENT :**

Reducing in clinical symptoms and by comparing the following parameters before and after treatment

1. Quantity of Menstrual blood flow based on PBAC score

2. Number of pads used for a cycle

3..Haemoglobin level.

**Medical Officer Signature:** **HOD**

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